Volume 2: ESRD Analytical Methods

Contents

Introduction

In the ESRD Methods chapter, we present details on the United States Renal Data System (USRDS) database, its standardized working datasets and specialized code definitions, and the common data processing practices applied to the data used in the production of this Annual Data Report (ADR). We also describe the statistical methods used in the ADR. The *Researcher's Guide to the USRDS Database,* available through www.usrds.org, provides additional information about the database and standard analysis files (SAFs). For this ADR, data are reported through December 31, 2013.

Data Sources

The USRDS maintains a relational database of diagnostic and demographic characteristics of end-stage renal disease (ESRD) patients including information on the incidence, prevalence, morbidity, and mortality of this population as well as biochemical lab results, dialysis and other institutional claims, physician/supplier services, treatment and payer histories, hospitalization and modality events, and details regarding providers. As the ESRD population are typically Medicare beneficiaries, the main data source for this database is the Centers for Medicare & Medicaid Services (CMS).

In 2003, the USRDS was expanded to include information on persons with chronic kidney disease (CKD). The data for CKD patients come from the National Health and Nutrition Examination Survey (NHANES) and billing data sources such as Medicare. In 2009 acute kidney injury (AKI) was added to the USRDS ADR in order to cover all stages of kidney disease.

This introduction traces the history of data collection for ESRD patients, and discusses the systems that have evolved to house the data. Detailed discussions about the data and analytical methods that are used in each chapter are found in the section titled *Analytical Methods Used in the ESRD Volume*.

In October 1972, by Public Law 92-603, which expanded the Social Security Act,[1] ESRD patients were included as beneficiaries in the Medicare Program. With the provision of insurance coverage for end-stage renal care now provided, a means of collecting

and utilizing data about that care was sought. The government made efforts to contract out a project to implement a national data collection system, or ESRD registry, between 1974 and 1977, but the effort was not successful. Meanwhile, Medicare expenditures and the number of ESRD beneficiaries began to grow significantly, and both government and the renal community became more concerned with the development of such a national registry.[2]

In accordance with the Privacy Act of 1974, which established a formal System of Records (SOR) for the protection of collected personal information such as name and Social Security number, a SOR was created for the ESRD program titled the "End Stage Renal Disease (ESRD) Program Management and Medical Information System (PMMIS) – SOR system number 09-70-0520.[3] This progress toward a data collection system, along with the 1975 and 1976 legislative amendments to the Social Security Act expanding Medicare coverage to ESRD patients, furthered the push for the development of a national ESRD Registry.

In 1977, the Health Care Financing Administration (HCFA), an agency that oversaw Medicare's financing (later renamed the Centers for Medicare & Medicaid Services (CMS)), was established under the department of Health Education and Welfare (HEW), which was renamed Health and Human Services (HHS) in 1979. CMS handles payment and administrative functions for all Medicare recipients on a regional (e.g., state) level. Originally, this was done through contracted intermediaries (Part A services) and carriers (Part B services). In recent years, the Parts A and B bill processing function has been combined into Medicare Administrative Contractors (MACs). Furthermore, CMS contracts with 18 regional ESRD Network offices that perform research and data collection activities, assure quality of medical care, and adjudicate patient grievances.

In June of 1978, Public Law 95-292 addressed the need for significant improvements to ensure cost-effective quality of care in the ESRD program. This finally led to the development of a comprehensive Medicare-based data system for the ESRD program within the

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[1] Public Law 92-603, Approved October 30, 1972. *www.gpo.gov/fdsys/ pkg/STATUTE-86/pdf/STATUTE-86-Pg1329.pdf*

[2] Blagg CR, Bovbjerg RR, Fitzsimmons SC. Here are (almost all) the data: The evolution of the U.S. Renal Data System. *Am J Kidney Dis* 1989;14(5): 347–353.
[3] *http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/CMS-Systems-of-Records.html*

HCFA.[4,5] Thus, the original data storage system was created and it was known by the same name as the official SOR title, the ESRD Program Management and Medical Information System (PMMIS). It was established to provide medical and cost information for ESRD program analysis, policy development, and epidemiologic research.[5]

The PMMIS gathered information on Medicare ESRD patients and Medicare-approved ESRD hospital-based and independent dialysis facilities. Data was compiled via Medicare claims and data forms that were collected through the Medicare intermediaries. The forms included the Medical Evidence form (CMS 2728), the Death Notification form (CMS 2746), and the Facility Survey form (CMS 2744). Other files maintained in the system included the Patient Identification File, the Transplant File, the Transplant Follow-up File, the Quarterly Dialysis File, and the Hospital Inpatient Stay Record File. There was no mandatory compliance for data collection, so early data is quite incomplete. In 1981, reporting on the incidence of ESRD was mandated as a requirement for Medicare Entitlement and a new Medical Evidence Form was introduced. Since that time there has been continuous improvement in the completeness of the data.[5] The PMMIS was maintained on HCFA computers, and was a batch-oriented Model 204 (M204 IBM Mainframe) data system.

Initially, HCFA was required to submit an annual report to Congress on the ESRD program and three reports were published (HCFA 1979, 1980, 1982). Due to the burden for HCFA of compiling many related reports, Congress rescinded the requirement for a separate report and the agency was permitted to include the ESRD program in its annual report on the whole Medicare program.[5] This level of reporting did not, however, adequately meet the needs of the renal community for reliable data collection and reporting on outcomes and quality of care. Throughout the 1980s, efforts continued to create a comprehensive ESRD registry with reporting beyond that which the PMMIS provided. This need was recognized politically as well as among researchers, and Congress, in 1986, called for the DHHS to establish a "national end-stage renal disease registry."[6] An interagency committee was formed between HHS and the National Institute of

Diabetes and Digestive and Kidney Diseases (NIDDK) and an RFP was shortly thereafter issued for the development of the United States Renal Data System (USRDS) to establish a complete ESRD Registry, which was to be built upon and surpass the HCFA data collected by the PMMIS. The contract was awarded by NIDDK in May 1988 to the Urban Institute, with a subcontract to the University of Michigan, and the first USRDS Annual Data Report on the ESRD population was released in 1989.

The specific data systems utilized by CMS to manage the ESRD database have evolved over the years as technology has changed and the need for improvements was identified. In 1995, CMS transitioned from the way data were stored in the original PMMIS, replacing its Medicare ESRD Support Subsystem (MESS) with an enhanced online M204 data system known as the Renal Beneficiary and Utilization System (REBUS). Also in 1995, non-Medicare patients began to be included in the database as the ESRD Medical Evidence Report form (CMS 2728) was again revised and made mandatory for all ESRD patients.

Renal Management Information System

In 2003, the REBUS database was converted into an Oracle relational database known as the Renal Management Information System (REMIS), and the Standard Information Management System (SIMS) database of the ESRD networks was also established. SIMS collected the CMS Medical Evidence, Death Notification, and Facility Survey forms mentioned above, and also included information to track patient movement in and out of ESRD facilities, and their transitions from one treatment modality to another. REMIS calculates Medicare ESRD coverage periods for renal patients and includes operational interfaces to the SIMS Central Repository and the Medicare Enrollment Database (EDB). REMIS also includes sophisticated data quality problem resolution support.[7]

CROWNWeb and Standard Information Management System Database

The Standard Information Management System (SIMS) database of the ESRD networks was established in 2003. It included information to track patient movement in and out of ESRD facilities, and their transitions from one treatment modality to

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4   Kidney Failure and the Federal Government, Richard A. Rettig and Norman G. Levinsky, Editors. National Academies of Sciences, 1991.

5   *http://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDNetwork Organizations/Downloads/ESRDNWBackgrounder-Jun12.pdf*

6   Omnibus Budget Reconciliation Act of 1986 – PL 99-509

7   *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/IdentifiableDataFiles/RenalManagementInformationSystem.html*

another. With the integration of the SIMS events data into the USRDS Database, it became possible to better track patients beyond the initiation of treatment. The SIMS events data, along with the mandate for the Medical Evidence form beginning in 1995, allowed for inclusion of patients for whom there previously were no data on initial modality or death. SIMS was replaced by CROWNWeb in 2012. CROWNWeb is a web-based data collection system that captures clinical and administrative data from Medicare-certified dialysis facilities, and allows authorized users to securely submit, update, and verify data provided to Medicare. This system was rolled out nationally in June 2012. In addition to replacing the patient tracking functionality of SIMS, CROWNWeb also collects new data to support calculation of clinical measures (e.g., Kt/V, hemoglobin, and calcium), and integrates these data with the REMIS system.

Thus, the USRDS Database contains demographic, diagnostic, and treatment history information for all patients with ESRD, regardless of whether they are Medicare beneficiaries. The data are updated on a regular basis using the Medicare EDB, ESRD Medical Evidence and Death Notification Report forms (CMS 2728 and 2746), Medicare Institutional and Carrier claims, and the Organ Procurement and Transplantation Network (OPTN) transplant database. CMS has also established data-integrity rules to ensure accurate identification of patients in the CMS databases.

CMS Medicare Enrollment Database

The Medicare EDB is the designated repository of all Medicare beneficiary enrollment and entitlement data, including current and historical information on beneficiary residence, Medicare as secondary payer (MSP) and employer group health plan (EGHP) status, and Health Insurance Claim/Beneficiary Identification Code cross-referencing. About 8% of persons in the USRDS database never qualify for Medicare benefits and thus do not enter the Medicare EDB. Information on these patients comes from CROWNWeb, OPTN, and the Social Security Administration (SSA) mortality database.

ESRD Medical Evidence Form (CMS 2728)

The CMS ESRD Medical Evidence Report form (CMS 2728) is used to register patients at the onset of ESRD, and must be submitted by dialysis or transplant providers within 45 days of treatment initiation. The

form establishes Medicare eligibility for individuals previously not Medicare beneficiaries, reclassifies previously eligible beneficiaries as ESRD patients, and provides demographic and diagnostic information on all new patients. The CMS, USRDS, and renal research communities rely on the form to ascertain patient demographics, primary cause of ESRD, comorbidities, and biochemical test results at the time of ESRD initiation. Prior to 1995, providers were required to file the Medical Evidence form only for Medicare-eligible patients. Since the 1995 revision, however, providers are required to complete the form for all new ESRD patients regardless of Medicare eligibility status.

The third major revision of the Medical Evidence form, in May 2005, remedied several shortcomings of the 1995 form and its earlier versions. Key additions target pre-ESRD care and vascular access use, and additional new fields collect information on glycosylated hemoglobin (HgbA1c) and lipid testing, on the frequency of hemodialysis (HD) sessions, and on whether patients are informed of transplant options.

ESRD Death Notification Form (CMS 2746)

The ESRD Death Notification form (CMS 2746) is used to report the death of ESRD patients. According to CMS policy, this form must be submitted by dialysis or transplant providers within 30 days of a patient's death, and provides the date and causes of death (primary and secondary), reasons for discontinuation of renal replacement therapy, if applicable, and evidence of hospice care prior to death. It is the primary source of death information for CMS and the USRDS, identifying more than 92% of deaths. The USRDS also utilizes several supplemental data sources for ascertaining death (see the *Death Date Determination* section below for more details).

Annual Facility Survey (CMS 2744)

Independent ESRD patient counts are available from the CMS Annual Facility Survey (AFS) (CMS 2744), which all Medicare-certified dialysis facilities must complete. The AFS reports the counts of patients being treated at the end of the year, new ESRD patients starting treatment during the year, and patients who die during the year. Both Medicare and non-Medicare end-of-year patients are counted. While AFS files do not carry patient-specific demographic and diagnosis data, they provide independent patient counts used to complement the CMS patient-specific records. In addition, CMS 2744 includes facility level information

such as ownership, services offered, number of stations, and detailed staffing data. Starting with the 2005 AFS, CMS stopped posting data from these surveys on the Internet. Beginning with the 2007 ADR, the USRDS extracted the relevant facility survey data directly from the SIMS database. Beginning in 2012, when SIMS was replaced by CROWNWeb, the USRDS received the facility survey data directly from CROWNWeb.

Organ Procurement and Transplantation Network Database

In the early 1980s CMS began collecting data on all Medicare kidney transplants in the PMMIS data system. In 1984, the National Organ Transplant Act established the Organ Procurement and Transplant Network (OPTN) to collect data and maintain a registry for organ matching and transplantation. These two efforts were consolidated in 1994, and only OPTN continued to collect data on transplant donors and recipients. In addition to these sources, transplants are also identified from Medical Evidence forms that indicate transplant as the initial modality, from CROWNWeb transplant events, and from institutional inpatient claims.

CMS Standard Analytical Files

The CMS Standard Analytical files (SAFs) contain billing data from final action claims submitted by Medicare beneficiaries with ESRD in which all adjustments have been resolved. The USRDS uses these SAFs to obtain data from institutional claims (Part A), including inpatient, outpatient, home health agency, hospice, and skilled nursing facility (SNF) claims as well as Physician/Supplier and Durable Medical Equipment (DME) (Part B) claims.

CMS SAFs are updated quarterly with a six month lag in complete data. Annual SAF files are completed each June for services incurred in the prior calendar year and processed through June of the current year (an 18-month window for each calendar year). The most current full year SAF that is released in June of each year is therefore complete through the end of the prior year. Files of claims occurring in the current year are created 6 months into the year, and are then updated quarterly. Claims also provide an additional source of data to those listed above, which is useful for determining important dates, such as first service dates, death dates, transplant dates, and transplant failure dates. The accuracy of patient and graft survival statistics is enhanced by considering all possible sources of these events.

CMS Prescription Drug Event File

In December 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), amending the Social Security Act by adding Part D under Title XVIII. With this new Part D coverage, health plans must submit a summary record called the prescription drug event (PDE) record to CMS whenever a Medicare beneficiary fills a prescription. Each drug is identified by a National Drug Index (NDC) code. The record also contains prescription dosage information, drug costs above and below the out-of-pocket threshold, other true out-of-pocket (TrOOP) amounts, plan paid amounts, and low-income cost sharing subsidy amounts. Due to delays in availability of more recent data, the USRDS 2015 ADR includes 2006–2011 PDE data.

CMS 5 Percent Standard Analytical Files

The CMS 5 percent general Medicare SAFs are a random sample of 5% of the entire Medicare population, and contain billing data from final action claims submitted for Medicare beneficiaries in which all adjustments have been resolved. CMS and its contractors produce the Medicare 5 percent datasets by selecting all final action claims for Medicare beneficiaries whose CMS Health Insurance Claim (HIC) number ends in 05, 20, 45, 70, or 95. These five two-digit pairs were randomly selected to create a sample containing 5% of the total number of Medicare beneficiaries (Merriman and Asper, 2007). The sample design has the effect of creating a built-in longitudinal panel dataset. Once in the sample, a beneficiary will remain a part of all future year data files until death or a change in HIC number. Since 2012, the USRDS has received the Master Beneficiary Summary File (formerly the Denominator file), containing demographic information on each beneficiary in the sample, as well as dates of enrollment in the various Medicare programs (Hospital Insurance [Part A], Supplemental Medical Insurance [Part B], Medicare Advantage managed care plans [Part C] and Prescription Drug Benefit [Part D]). Institutional claims for beneficiaries in the Medicare 5 percent sample are received in five files, based on type of medical service: inpatient, outpatient, home health agency, hospice, and skilled nursing facility (SNF). Physician and supplier claims (also referred to as Carrier Claims) are comprised of one file for durable medical equipment and another file for all other Part B covered services. These files collectively are referred to as the Medicare 5 percent files in the ADR. The 5 percent files are used to

construct CKD, diabetes, and congestive heart disease cohorts based on billing data. The total Medicare 5 percent sample is used to develop total Medicare cost and utilization data for comparison purposes.

CMS Dialysis Facility Compare Data

The USRDS uses the CMS Dialysis Facility Compare data to define corporation name and ownership type for each renal facility. Prior to the 2003 ADR, similar data were extracted from the Independent Renal Facility Cost Report (CMS 265-94).

CDC Surveillance

The CDC used its National Surveillance of Dialysis-Associated Diseases to collect data from the United States dialysis facilities on patient and staff counts, membrane types, reuse practices, water treatment, therapy, vascular access use, antibiotic use, hepatitis vaccination and conversion rates, and the incidence of HIV, AIDS, and tuberculosis. No data are patient-specific. CDC survey data are available for the years 1993 through 1997 and 1999 through 2002. The CDC did not conduct a survey in 1998, and terminated this program after 2002.

United States Census

In rate calculations throughout this year's ADR we use data from the 2000 and 2010 U.S. Census, and also incorporate CDC population estimates by race. Estimates for 1990–1999 were back-calculated based on the actual 2000 census. Later data, however, include racial groups that do not coincide with those in the ESRD data. For rate calculations throughout the ADR, we use the CDC's Bridged Race Intercensal and Postcensal Population Estimates Dataset, which estimates White, Black/African American, Native American, and Asian populations. The data and methods for these estimates are available at *http://www.cdc.gov/nchs/nvss/bridged_race.htm*. For state and network rates, we use Vintage 2013 Bridged-Race Postcensal Population Estimates. Both CDC Bridged-Race Intercensal and Postcensal Population Estimates Datasets are available at *http://www.cdc.gov/nchs/nvss/bridged_race/data_documentation.htm*.

Database Definitions

ESRD Patient Determination

A person is identified as having ESRD when a physician certifies the disease on the Medical Evidence form (CMS 2728), or when there is other evidence of chronic dialysis or a kidney transplant. Patients with acute kidney failure who are on dialysis for days or weeks, but who subsequently recover kidney function, are excluded from the database if their Medical Evidence forms have not been submitted.

The ESRD first service date is the single most important data element in the USRDS Database, and each patient must, at a minimum, have a valid first service date. This date is used to determine the incident year of each patient and the first year in which the patient is counted as prevalent.

In most cases, the first service date is derived by identifying the earliest date of any of the following potential indicators:

- The start of dialysis for chronic kidney failure as reported on the Medical Evidence form

- The first CROWNWeb event

- A kidney transplant as reported on a CMS or OPTN transplant form, a Medical Evidence form, or a hospital inpatient claim

- The first Medicare dialysis claim

There are two exceptions to the first ESRD service date determination:

- If the CROWNWeb event and Medical Evidence form agree (within 30 days of each other) and are more than 90 days after the first Medicare dialysis claim, and, if there is no transplant event between the first dialysis claim and the earlier of either the CROWNWeb event date or Medical Evidence form date, then first service date is defined as the earlier of the CROWNWeb event date or the Medical Evidence form date.

- If the Medical Evidence form date is one year earlier than the first CROWNWeb event date, and if the first claim date or first transplant date agrees with the first CROWNWeb event date, then the CROWNWeb first event date is used as the first service date.

Death Date Determination

After the ESRD first service date, the date of death is the most critical piece of information in the ESRD database. Death dates are obtained from several sources, including the CMS Medicare EDB, CMS forms 2746 and 2728, the OPTN transplant follow-up form, CROWNWeb database, inpatient claims, and, where allowed by regulation, the Social Security Death Master File. Because multiple sources report death information

for the same patient, one patient may have several reported dates. For these patients, we primarily use the median of the various death dates reported. However, in the small number of cases where there are only two death dates and they are more than 70 days apart, we use, instead, the most recent of the two dates.

Transplant Dates

The CMS and OPTN transplant data files overlap for 1988–1993, and transplants can also be identified from Medical Evidence forms that indicate transplant as the initial modality, from CROWNWeb transplant events, and from institutional inpatient claims. To resolve any conflicts among these sources, and create a complete list of unique transplant events, the USRDS has adopted the following procedure.

We start with the complete list of transplant events according to a single source (CMS before 1988 and OPTN after 1988). We then supplement this list using other data sources, only adding an event if we are reasonably certain the event is not already included. Specifically, we only add an event if there is no existing event within 30 days of the potential new event. We supplement first with CMS REMIS/REBUS/PMMIS data after 1988 (available until 1994), followed (in order) by Medical Evidence forms, inpatient Medicare claims records, and CROWNWeb patient events. Currently, more than 99% of transplant dates come from the OPTN data.

Graft Failure

We assume a graft failure date reported in the OPTN transplant follow-up or REMIS identification file is correct unless death or a new transplant occurs before this date. A graft failure date may not be recorded in either file. In this case, we use the earliest of the following events:

- Death

- Subsequent transplant

- Return to regular dialysis, indicated by a continuous period of dialysis billing records covering a minimum of 60 days with at least 22 reported treatments

- Return to dialysis reported on the Medical Evidence form

- Date of graft nephrectomy from the OPTN follow-up record or a Medicare claim

Medicare and Non-Medicare Patients

Beneficiaries are enrolled in Medicare based on criteria defined in Title XVIII of the Social Security Act of 1965, and in subsequent amendments to the act. A person who meets one of these four criteria is eligible to apply for Medicare: aged 65 and over, who has certain disabilities and illnesses, who has ESRD, or who is eligible for services of the Railroad Retirement Board.

Most ESRD patients are eligible to apply for Medicare as their primary insurance payer. Some, however, are not immediately eligible for Medicare coverage because of their employment status and pre-existing primary insurance benefits. These patients are usually covered by employer group health plans (EGHPs) and typically must wait 30–33 months before becoming eligible to have Medicare as their primary payer. Some of these patients, particularly new patients since 1995, have first service dates established by Medical Evidence forms or CROWNWeb events, but have no dialysis claims or hospitalization events in the CMS claims database. In the REMIS database, all non-Medicare ESRD patients are assigned a code of 'ZZ' in the two-character Beneficiary Identification Code field. CMS does not generally include these patients in the datasets released to researchers.

The USRDS recognizes that these non-Medicare patients are true ESRD patients and should be included in patient counts for incidence, prevalence, and modality, as well as mortality and transplant rate calculations. Calculations of hospitalization statistics, as well as expenditure rates, should not include these patients because of the small number of claims available in the first 30–33 months after their first ESRD service.

The USRDS, in working with CMS, has been able to resolve most of the non-Medicare ESRD patients since the release of the ESRD Patient Database, REMIS, in the fall of 2003. According to our most recent assessment—performed during production of the 2007 ADR—we have determined that at least 99% of these patients have been resolved due to significant advancements in the REMIS database system.

Integration of the CROWNWeb and CMS Claims Databases

The USRDS uses all available data to create a treatment history for each patient in the database,

including all modality events, their duration, and the renal providers involved in each patient's care. The CROWNWeb event database is the primary source of the modality sequence file, and the dialysis claims are used as a way of confirming placements and identifying problem cases. As described in previous sections, we use all available sources to determine first service dates, deaths, transplants, and graft failures.

For patients who either do not appear in the CROWNWeb events file or for whom the only event is "New ESRD Patient," and patients who have gaps in treatment history after transferring out of a facility, the Medicare dialysis claim file is used. For "Transfer Out" and "Transfer Out for a Transplant" events followed by large gaps in treatment history (seven days or more), claims falling in gaps are included, with the exception that no claims data are included if the "Transfer Out for a Transplant" event has a corresponding transplant/transplant failure event that occurred within 30 days (either before or after the event). Claims data are also included for the periods after "Transplant Failure" events and "Discontinued Dialysis" modality if the periods are longer than seven days.

Because the claims data capture the modality "Center Self-Hemodialysis" more accurately than the CROWNWeb data, this claims-based designation overrides other dialysis modalities from CROWNWeb. Any CROWNWeb dialysis event that falls into a "Center Self-Hemodialysis" period as determined by claims is recoded as "Center Self-Hemodialysis."

Some events that do not make sense are removed. These include events that occur before a patient's first service date, those falling between "Transplant" and "Transplant Failure," and "Transfer Out for A Transplant" events that occur 60 days or less after the corresponding "Transplant."

We have identified errors in the CROWNWeb data modality conversion that cause the wrong coding for peritoneal dialysis (PD) subcategories, including continuous ambulatory PD (CAPD), continuous cycling PD (CCPD), and intermittent PD (IPD). To correct this problem, we employ historical data (pre-CROWNWeb conversion) for years prior to 2012, and a combination of historical data and more complete CROWNWeb data for 2012. CROWNWeb data is used exclusively for years 2013 and beyond.

Lost-to-follow-up Methodology

Gaps frequently exist in the CROWNWeb and billing data upon which modality periods are based. The USRDS assumes that a modality continues until death or the next modality-determining event. A patient with a functioning transplant is assumed to maintain it until graft failure, as defined in the *Graft Failure* section above, occurs. A dialysis modality, in contrast, is assumed to continue for only 365 days from the date of the last claim, in the absence of a new CROWNWeb event, a transplant date, a death date, or dialysis claims. After this period, the patient is declared lost-to-follow-up, until the occurrence of a new CROWNWeb event, dialysis claim, or transplant event.

Patients are considered lost-to-follow-up beginning 365 days after a "Transplant Failure" event or "Discontinued Dialysis" modality with no subsequent events. Patients for whom the only event is a first service date, and who do not exist in any other files were also treated as lost-to-follow-up, beginning one year after the first service date. A number of events can result in a lack of dialysis data and eventual reclassification of a patient as lost-to-follow-up:

- The patient may have recovered renal function (RRF) and no longer have ESRD. For a valid patient classification, this event must occur within 180 days of the first service date, and the RRF period must persist for at least 90 days.

- The patient may no longer reside in the United States.

- The patient's death may not have been reported to the Social Security Administration or to CMS.

60-day Stable Modality Rule: Treatment History

The 60-day stable modality rule requires that a modality continue for at least 60 days before it is considered a primary or switched modality. The rule is used to construct a second modality sequence, or treatment history, for each patient and assigns the patient a modality only if it is a stable or established modality. The hospitalization statistics shown by modality in the ADR use the 60-day rule to define a stable modality. Most of the other data reported in the ADR do not apply this rule.

90-day Rule: Outcomes Analyses

This rule defines each patient's start date for data analyses as day 91 of ESRD and is used primarily to calculate hospitalization rates.

Serum Albumin Data

The Medical Evidence form reports patient albumin levels along with the test's lower limit, which indicates the testing method: bromcresol purple or bromcresol green, with lower limits of 3.2 and 3.5 g/dL, respectively.

In producing the 2004 ADR, USRDS found that in 1995–2003, almost 50% of patient forms contained lower limit values equal to "zero," while another 25% reported values other than the expected 3.2 and 3.5 g/dL. Only 25% (n=173,000) of incident patients had legitimate lower limit values. Further analyses, however, showed that these patients form a representative cohort sample, with demographic distributions by age, sex, race, and cause of ESRD similar to those of the overall ESRD population. For all figures in the 2005 and subsequent ADRs that present serum albumin data from the Medical Evidence form, the USRDS ESRD Database includes only those incident patients with both an albumin lower limit of 3.2 or 3.5 g/dL and an albumin value.

Modalities

USRDS and CMS have worked extensively on methods of categorizing patients by ESRD treatment modality. The initial modality for a patient is determined using an algorithm based on a hierarchy of data sources. The hierarchy of sources is evaluated in the following order: CROWNWeb data, Medical Evidence form, claims data, and transplant data. The modality indicated in Medical Evidence form may be temporary, as patients often change to a new one during the first 90 days of treatment, and it can be difficult to track modality during this time. Patients aged 65 and older have Medicare claims in the first 90 days that contain revenue codes designating modality. Patients younger than 65 and in EGHPs or Medicare risk programs, however, have no such early claims. Thus, modality may not be determined until Medicare becomes the primary payer at day 91 or, for EGHP patients, at 30–33 months after the ESRD first service date. These limitations influence our ability to determine a patient's modality at any one point in time.

Of note are patients categorized as having an unstable modality (i.e., on a modality for fewer than 60 consecutive days) in the first 90 days of treatment. Because these patients tend to have higher death and hospitalization rates, interpretations of modality-specific outcome data including them

should be viewed with caution. These patients are not recognized as being either stable HD or stable PD patients in analyses of patients with stable modality (e.g., hospitalization rates in this ADR). When the 60-day stable modality rule is used, these patients are included in the "all ESRD" category, which provides a more complete view of outcomes with the least biasing of the data.

As mentioned earlier, a new modality/event— recovered renal function (RRF)—was introduced in the 2007 ADR. This event can be established only if it occurs within the first 180 days following the first service date, and if the RRF period persists for at least 90 days. The RRF event is similar to the lost-to-follow-up event in that patients will not be included in the prevalent populations for outcomes analyses. However, as with lost-to-follow-up events, we retain them in the modality sequence so that subsequent renal failure episodes can be tracked closely and in a timely manner.

ESRD treatment modalities may be categorized in different ways within the analyses in each chapter; these are defined in the chapter-specific analytical methods sections that follow this section.

Payers

Information on payers is obtained from the Medicare EDB. We also examine Medicare outpatient claims to identify patients for whom the EDB does not indicate Medicare as primary payer (MPP) but who have at least three consecutive months of dialysis treatment covered by Medicare; these patients are also designated as having MPP coverage. From these two data sources we construct a payer sequence file to provide payer history, and, beginning with the 2003 ADR, we use this file to identify Medicare eligibility status and other payers. The construction of this file is similar to that of the treatment history file. Payer status is maintained for each ESRD patient from the ESRD first service date until death or the end of the study period. Payer status information prior to the start of ESRD (ESRD first service date) is available from the backcasted payer sequence file. This payer sequence file is similar to the standard ESRD payer service file, except that the pre-ESRD payer sequence file begins at the first evidence of Medicare enrollment from the Enrollment Database, rather than first ESRD service date, as is the case with the ESRD payer sequence. The pre-ESRD payer sequence ends the day before the first ESRD service date. Payer data are used to categorize a patient as

MPP, Medicare as secondary payer (MSP) with EGHP, MSP non-EGHP, Medicare Advantage (Medicare + Choice), Medicaid, or a combination of payers (see the *Researcher's Guide to the USRDS Database* for details). With this approach, the USRDS is now able to apply payer status information in all outcome analyses using the "as-treated" model (see the discussion in *Chapter 11: Medicare Expenditures for Persons With ESRD*).

PRIMARY CAUSE OF RENAL FAILURE

Information on the primary cause of renal failure is obtained directly from the Medical Evidence form. For the ADR, we use eight categories with corresponding ICD-9-CM codes as follows:

- Diabetes: 250.00, 250.01, 250.40, 250.41

- Hypertension: 401.0, 401.1, 401.9, 403.0, 403.1, 403.9, 403.91, 404.0, 404.1, 404.9, 440.1, 593.81, and 593.83

- Glomerulonephritis: 283.1, 283.11, 287.0, 443.1, 446.0, 446.2, 446.21, 446.29, 446.4, 580.0, 580.4, 580.9, 581.1, 581.8, 581.9, 582.0, 582.1, 582.9, 583.1, 583.2, 583.21, 583.22, 583.4, 583.81, 583.82, 583.9, 583.91, 583.92, 695.4, 710.0, and 710.1

- Cystic kidney: 583.9, 753.1, 753.13, 753.14, and 753.16

- Other urologic: 223.0, 223.9, 274.1, 590.0, 591.0, 592.0, 592.9, 599.0, and 599.6

- Other cause: 016.0, 042.0, 042.9, 043.9, 044.9, 135.0, 189.0, 189.1, 189.9, 202.8, 202.83, 202.85, 202.86, 203.0, 203.08, 239.50, 239.51, 239.52, 270.0, 271.8, 272.7, 273.3, 274.1, 274.11, 275.4, 275.49, 277.3, 282.6, 282.61, 282.62, 282.63, 282.69, 282.83, 282.86, 287.3, 446.6, 572.4, 580.89, 582.89, 583.0, 583.6, 583.7, 583.89, 584.5, 587.0, 591.8, 590.9, 593.89, 593.9, 599.0, 639.3, 646.2, 714.0, 728.89, 753.0, 753.2, 753.21, 753.22, 753.29, 753.3, 753.39, 756.7, 756.71, 759.5, 759.8, 759.89, 866.0, 965.4, 965.9, 977.8, 982.8, 984.9, 996.8, 996.81, 996.82, 996.83, 996.84, 996.85, 996.86, 996.87, and 996.89

- Unknown cause: 239.5, 428.0, 500.0, 582.0, 586.0, 489.9, 589.0, 589.1, 589.9, 592.1, 593.1, 799.9, 799.99, 888.88, 899.9, 999.99, 999.9, and ICD-9-CM codes not covered by the lists of codes above

- Missing cause: no ICD-9-CM code listed

RACE AND ETHNICITY

Data on patient race and ethnicity are obtained from the Medical Evidence form, the CMS Medicare Enrollment Database, the REMIS patient identification file, and the CROWNWeb patient roster. Because they are addressed in separate questions on the Medical Evidence form, patients can be assigned a racial category and an ethnic category independently. Patient ethnicity became a required field on the 1995 revised Medical Evidence form, but because the form did not go into effect until midway through 1995, data for 1995 are incomplete. Therefore, information on Hispanic patients is presented starting in 1996. The non-Hispanic category includes all non-Hispanics and patients with unknown ethnicity. Because of the small number of ESRD patients of some races, as well as how race is categorized in the U.S. Census data, we concentrate on White, Black/African American, Native American (including Alaskan Native), and Asian (including Pacific Islander) populations. Data on patients of other races will be presented as their numbers increase. Beginning with the 2016 ADR, the Hispanic and race fields will be combined to clarify differences between Hispanic and non-Hispanic Whites.

Analytical Methods Used in the ESRD Volume

Data sources are indicated in the footnotes of each table and figure in Volume 2: End-Stage Renal Disease (ESRD) in the United States. Additional information on these sources is also available in the *Data Sources* section above. Methodology used for the figures and tables in Volume 2 is described below in the corresponding chapter or *ESRD Reference Table Methods* section. When figure or table data come directly from a particular Reference Table, please refer to the appropriate Reference Table methods section for additional detail.

CHAPTER 1: INCIDENCE, PREVALENCE, PATIENT CHARACTERISTICS, AND TREATMENT MODALITIES

Incidence and Prevalence

Here and throughout the ADR, the USRDS generally reports point prevalence as of December 31, while period prevalence is reported for a calendar year. Annual period prevalent data thus consist both of patients who have the disease at the end of the year and those who have the disease during the year and die before the year's end. Because the USRDS treats successful transplantation as a therapy rather than as a "recovery" from ESRD, patients with a functioning transplant are counted as prevalent patients.

Because data are available only for patients whose ESRD therapy is reported to CMS, we qualify the terms incidence and prevalence as incidence and prevalence of reported ESRD. Some ESRD registries use the term "acceptance into ESRD therapy." We believe, however, that "incidence of reported ESRD therapy" is more precise, because "acceptance" implies that remaining patients are rejected, when they may simply not be identified as ESRD cases or may not be reported to CMS. Beginning with the 1992 ADR, lost-to-follow-up patients are not included in the point prevalent counts; they are, however, reported in Table B.1 of the Reference Tables.

Rate adjustments in this chapter are as follows: overall rates (including those in the maps) are adjusted for age, sex, and race; rates by age are adjusted for sex and race; rates by race or ethnicity are adjusted for age and sex; and rates by primary cause of ESRD are adjusted for age, sex, and race. Direct adjustment as described in the *Statistical Methods* section of the chapter was used. Census data rate and prevalence calculations are now based on intercensal estimates; for details, see the section on the *United States Census* in the *Data Sources* section of this chapter.

For Figures 1.4–1.7, incident cases and incidence rates are taken directly from Reference Table A. More specifically, cases come from A.1 and rates come from A.2(2) and A.2(3). Similarly, data for Figures 1.13–1.16 come directly from Reference Table B. Specifically, prevalent cases correspond to those found in B.1 and prevalence corresponds to that found B.2(2) and B.2(3). For details on the methods used, refer to the sections for Reference Tables A and B and the section for statistical methods used for rate calculations.

Figures 1.21 and 1.23 report the home dialysis patient distribution, by therapy type and among incident and point prevalent populations, respectively.

For all maps by HSA, data were suppressed for HSAs with less than 11 cases.

Patient Care and Laboratory Values

For Tables 1.4, 1.5, and 1.6, and Figures 1.17, 1.18, 1.19, and 1.20, laboratory values and treatment characteristics were derived from questions on the Medical Evidence form. All eGFR values are calculated using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation from data acquired from the Medical Evidence form.

Treatment Modalities

Modality figures and the associated Reference Tables describe the treatment modalities of all known ESRD patients, both Medicare and non-Medicare, who are not classified as lost-to-follow-up or as having recovered renal function (RRF). The RRF event, introduced in the 2007 ADR, is defined as an event that occurs within the first 180 days of ESRD initiation and lasts for at least 90 days. By definition, patients classified as having RRF post-initiation are included in the incident counts. Unless noted otherwise, incident and point prevalent cohorts without the 60-day stable modality rule are used in the analyses. Treatment modalities are defined as follows:

- Center hemodialysis: HD treatment received at a dialysis center

- Center self-hemodialysis: HD administered by the patient at a dialysis center; a category usually combined with center HD

- Home hemodialysis: HD administered by the patient at home; cannot always be reliably identified in the database

- CAPD: continuous ambulatory peritoneal dialysis; usually combined with CCPD and other PD

- CCPD: continuous cycling peritoneal dialysis; usually combined with CAPD and other PD

- Peritoneal dialysis: analyses typically consist of CAPD, CCPD and intermittent peritoneal dialysis (IPD)

- Other peritoneal dialysis: primarily IPD, a small category except among very young children; usually combined with CAPD and CCPD to form PD category

- Uncertain dialysis: a period in which the dialysis type is unknown or multiple modalities occur but do not last 60 days; usually combined with unknown dialysis to form an other/unknown dialysis category

- Unknown dialysis: a period in which the dialysis modality is not known (e.g., when dialysis sessions are performed in a hospital); usually combined with uncertain dialysis to form an other/unknown dialysis category

- Renal transplantation: a functioning graft from either a living donor (a blood relative or other living person) or a deceased donor

- Death: a category not appearing in the year-end

modality tables, which report only living patients, but used as an outcome (e.g., in tables showing living patients followed for a period of time for their modality treatment history)

Facilities began submitting patient data via CROWNWeb beginning in 2012. This information was previously submitted by facilities via the ESRD Networks. The new method of data input and submission may lead to unanticipated changes in trends beginning in 2012.

CHAPTER 2: HEALTHY PEOPLE 2020

Objective CKD-3

Increase the proportion of hospital patients who incurred acute kidney injury who have follow-up renal evaluation in 6 months post-discharge

Data for this objective include all patients in the Medicare 5 percent sample who are aged 65 and older and who have hospitalized acute kidney injury (AKI) events in the given year (1992–2012). Hospitalized AKI is defined by the presence of ICD-9-CM diagnosis code 584 in any field of the inpatient claims, and renal evaluation is identified by a microalbumin test. Patients are followed from the discharge date to the earliest date of death, ESRD, end of Medicare coverage, or six months after the discharge date. CPT codes for urinary microalbumin measurement are identified from HEDIS 2008 specifications (HEDIS 2008, an NCQA program, is used to monitor the performance of managed health care plans), and include 82042, 82043, 82044, and 84156.

Objective D-12

Increase the proportion of persons with diagnosed diabetes who obtain an annual urine albumin measurement

The cohort includes general Medicare patients diagnosed with diabetes mellitus (DM) in each year, continuously enrolled in Medicare Parts A and B during the whole year, and aged 65 or older at the beginning of the year. CPT codes for urinary microalbumin measurement are those used in Objective CKD-3, above. Testing is tracked during each year. Diabetes is defined by a qualifying ICD-9-CM diagnosis code of DM on one or more Part A institutional claims (inpatient, skilled nursing facility, or home health agency), or two or more institutional outpatient claims and/or physician/supplier claims within a one-year observation period. Qualifying ICD-9-CM codes for diabetes mellitus are as follows: 250. XX, 357.2, 362.0X, and 366.41.

Objective CKD-4.1

Increase the proportion of persons with chronic kidney disease who receive medical evaluation with serum creatinine, lipids, and urine albumin

The cohort here is similar to that used for Objective D-12, but includes all CKD patients. Testing is tracked during each year. Patients are excluded if they are enrolled in a managed care program (HMO), acquire Medicare as secondary payer, are diagnosed with ESRD during the year, have a missing date of birth, or do not live in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories. Racial and ethnic categories are mutually exclusive. Methods of defining CKD are described in the CKD Analytical Methods chapter of Volume 1: Chronic Kidney Disease (CKD) in the United States. Serum creatinine is identified through CPT codes 80047–80050, 80053–80054, 80069, and 82565, while lipid testing is identified through CPT codes 80061, 82465, 82470, 83695, 83705, 83715–83721, 84478, 83700, 83701, and 83704. CPT codes for urinary microalbumin measurement are the same as those used for Objective CKD-3 above.

Objective CKD-4.2

Increase the proportion of persons with Type 1 or Type 2 diabetes and chronic kidney disease who receive medical evaluation with serum creatinine, urine albumin, HgbA1c, lipids, and eye examinations

Methods and codes used to determine rates of HbA1c testing and eye examinations are taken from HEDIS 2008 specifications. CPT codes 83036 and 83037 are used to identify HbA1c testing. Codes used to identify diabetic eye examinations are as follows: CPT codes, 92002, 92004, 92012, 92014, 92018, 92019, 92225, 92226, 92230, 92235, 92240, 92250, 92260, 67101, 67105, 67107, 67108, 67110, 67112, 67141, 67145, 67208, 67210, 67218, 67227, 67228, 67028, 67030, 67031, 67036, 67038, 67039, 67041, 67042, 67043, 67113, 67121, 67221, 67228, S0625, S0620, S0621, and S3000; ICD-9-CM procedure codes, 14.1–14.5, 14.9, 95.02, 95.03, 95.04, 95.11, 95.12, and 95.16; and ICD-9-CM diagnosis code V72.0. The cohort is similar to that used for Objective CKD-4.1, but includes all diabetic CKD patients. Methods of defining DM are described in the CKD Analytical Methods chapter Volume 1: Chronic Kidney Disease (CKD) in the United States.

Objective CKD-8

Reduce the rate of new cases of end-stage renal disease

Incident rates are calculated using the methods described for Chapter 1. Overall rates are adjusted by age, sex, and race; rates by age are adjusted for sex and

race; rates by sex are adjusted for age and race; and rates by race and ethnicity are adjusted by age and sex.

Objective CKD-9.1

Reduce kidney failure due to diabetes

Rates of kidney failure due to DM are also calculated using the methods described for Chapter 1, and adjustments are the same as those described for Objective CKD-8, above.

Objective CKD-9.2

Reduce kidney failure due to diabetes among persons with diabetes

This table uses data from the National Health Interview Survey; all ages are included. Three-year data are used to estimate the prevalence of DM in the middle year, and the size of the population with DM is based on U.S. census data. The incident rate per million of ESRD caused by DM is calculated as the number of incident ESRD patients with a primary cause of ESRD of DM, divided by the size of the population with DM in that group.

Objectives CKD-10 & CKD-11.3

Increase the proportion of chronic kidney disease patients receiving care from a nephrologist at least 12 months before the start of renal replacement therapy

Increase the proportion of adult hemodialysis patients who use arteriovenous fistulas or have a maturing fistula as the primary mode of vascular access at the start of renal replacement therapy

These tables use data from the newest version of the Medical Evidence form. The cohorts include incident HD patients, with CKD-11.3 limited to those aged 18 and older at initiation who have a known vascular access at that time. CKD-10 includes only patients for whom it is known whether they saw a nephrologist prior to initiation.

Objectives CKD-11.1 & CKD-11.2

Increase the proportion of adult hemodialysis patients who use an arteriovenous fistula as the primary mode of vascular access Decrease the proportion of adult hemodialysis patients who use catheters as the only mode of vascular access

These tables use data from CROWNWeb. The cohort includes prevalent HD patients from 2012 and 2013,who are aged 18 and older. Access type represents the last access type used in the year, according to CROWNWeb data.

Objective CKD-12

Increase the proportion of dialysis patients wait-listed and/or receiving a deceased donor kidney transplant within 1 year of end-stage renal disease start (among patients under 70 years of age)

The cohort includes patients from 2000–2013 who are younger than 70 at the initiation of ESRD. Percentages are calculated as the number of patients placed on the deceased donor organ waiting list or receiving a deceased donor transplant within one year of initiation, divided by the number of patients without a living donor available (i.e., patients receiving a living donor transplant are excluded), and are estimated using the Kaplan-Meier methodology.

Objective CKD-13.1

Increase the proportion of patients receiving a kidney transplant within 3 years of end-stage renal disease

The cohort includes patients from 1998–2010 who are younger than 70 at the initiation of ESRD. Patients are followed from ESRD certification to transplant, censoring at death or three years after the initiation of ESRD. Percentages are calculated using the Kaplan-Meier methodology.

Objective CKD-13.2

Increase the proportion of patients who receive a pre-emptive transplant at the start of end-stage renal disease

The cohort includes patients from 2001–2013 who are younger than 70 at the initiation of ESRD. Pre-emptive transplants are those in which ESRD initiation date is the date of transplant. Percentages are calculated as 100 (N/D), where N=the number of preemptive transplants in the year and D=the number of ESRD patients in the year.

Objectives CKD-14.1 & CKD-14.3

Reduce the total death rate for persons on dialysis

Reduce the cardiovascular death rate for persons on dialysis

Cohorts for these tables include period prevalent dialysis patients in each calendar year, 2001–2013, whose first ESRD service date is at least 90 days prior to the beginning of the year (point prevalent patients on January 1) or who reach day 91 of ESRD treatment during the year (incident patients). We exclude patients with unknown age or sex and those with an age calculated to be less than zero, as well as patients who are not residents

of the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories. Age is calculated on January 1, and race is defined from the Medical Evidence form. Cardiovascular mortality is defined using codes from past and current Death Notification forms: 01, 02, 03, 04, 1, 2, 3, 4, 23, 25, 26, 27, 28, 29, 30, 31, 32, 36, and 37. Patients are followed from January 1 (for point prevalent dialysis patients) or day 91 of ESRD (for incident dialysis patients) until death, transplant, or December 31 of the year. Rates are estimated as the number of patients who die from any cause (Objective 14.1) and who die from cardiovascular disease (Objective 14.3) in each year, per 1,000 patient years at risk.

Objective CKD-14.2

Reduce the death rate in dialysis patients within the first 3 months of initiation of renal replacement therapy

Cohorts here include incident dialysis patients in each calendar year, 2001–2013. In addition to applying the same exclusion criteria described for Objectives 14.1 and 14.3, we further exclude patients with recovered kidney function. Age is calculated on the first ESRD service date. Patients are followed from the first service date until death, transplant, or 90 days after ESRD. Rates are estimated as the number of patients who die from any cause per 1,000 patient years at risk.

Objectives CKD-14.4 & *CKD-14.5*

Reduce the total death rate for persons with a functioning kidney transplant

Reduce the cardiovascular death rate in persons with a functioning transplant

Patient cohorts here include period prevalent transplant patients, 2001–2013, whose first ESRD service date is at least 90 days prior to the beginning of the year (point prevalent patients on January 1) or who reach day 91 of ESRD treatment (incident patients). Exclusion criteria are the same as those described for Objectives 14.1 and 14.3. Patients are followed from January 1 (for point prevalent dialysis patients) or day 91 of ESRD (for incident dialysis patients) until death or December 31 of the year. Rates are estimated as the number of patients who die from any cause (Objective 14.4) and who die from cardiovascular disease (Objective 14.5) in each year, per 1,000 patient years at risk.

Chapter 3: Clinical Indicators and Preventive Care

In Figure 3.1, all data are obtained from CROWNWeb clinical extracts for December 2014. The adequacy

(Kt/V) analyses are restricted to patients at least 18 years old as of December 1, 2014. Patients must have been alive as of December 31, 2014, and must have had ESRD for at least one year as of the time of the measurement. If multiple measurements were available for a patient, the last one in the month was used. In Figure 3.1.b, all adult (aged 18 and older) patients who are on dialysis for at least 90 days as of December 1, 2014, and alive as of December 31, 2014, are included. If multiple hemoglobin measurements were available for a patient, the last one in the month was used. The categorical distribution of hemoglobin is shown for both HD and PD patients. In Figure 3.1c, the hypercalcemia measure was calculated as a 3 month rolling average for both HD and PD patients, who were alive as of December 31, 2014, and had ESRD for at least 90 days as of the time of measurement of an uncorrected serum calcium value.

Anemia Treatment

All of the findings in this section are based on Medicare claims data. Efforts have been made for the figures and tables to be as fully representative as possible of the U.S. dialysis patient population represented by CMS claims data, resulting in substantially larger sample sizes in some of the tables associated with this anemia section as compared with the 2014 ADR. The modality of the patient in each month is determined from the primary modality that is indicated on the claims file associated with each claim for hemoglobin, iron dose, and epoetin alfa (EPO) dose variables in the given month. For transfusion analyses, patients were assigned to HD or PD if having at least one claim for HD or PD therapy, respectively, in that month. There were very few patients having dual modality use within the same month.

Calculation of hemoglobin levels are shown in Figures 3.2, 3.3, 3.8, and 3.9. Hemoglobin values were based upon the first reported claim in each month for HD patients (Figures 3.2, 3.3) or for PD patients (Figure 3.8, 3.9). When hemoglobin levels were not available in claims data, hematocrit values, if available, were divided by 3 to serve as a proxy estimate. Patients were excluded in a given month if the hemoglobin level (or hemoglobin values estimated from hematocrit values) was <5 g/dL or >20 g/dL. Results are shown for erythropoiesis-stimulating agent (ESA)-treated patients in Figures 3.2, 3.3, 3.8, and 3.9, in which case analyses were restricted to patients who: (1) within the indicated month had a claim for ESA use and a claim for either hemoglobin or hematocrit level, and (2) at

the start of the month, were on dialysis for 90 days or more and were aged 18 or older. In Figures 3.2 and 3.8, hemoglobin levels are also provided for all patients, and the same restrictions were used as described in statement 2 above, but not limited to patients with an ESA claim within the given month in 2012. In addition, hemoglobin levels for patients not on any ESA drugs in a month were also shown for HD patients (Figure 3.2) and PD patients (Figure 3.8).

Calculation of mean EPO dose levels is shown in Figures 3.2 and 3.8. Mean monthly EPO dose is provided for HD patients in Figure 3.2 and for PD patients in Figure 3.8. Mean monthly EPO dose is shown for patients who within a given month had an EPO claim, were on dialysis for 90 days or longer, and were 18 years and older at the start of the month. EPO dose is expressed as mean EPO units per week, averaged over all EPO claims within a given month. Patients were excluded from these calculations for a given month if their monthly average EPO dose was either less than 250 units per week (resulting in 0.4% being excluded) or if their monthly average EPO dose was greater than 400,000 units per week; these criteria resulted in <0.001% of patients being excluded.

Calculation of intravenous iron use is shown in Figures 3.4 and 3.10. Intravenous iron use and IV iron dose for HD patients is presented in Figure 3.4 and for PD patients in Figure 3.10. Monthly intravenous iron use was among patients on dialysis for 90 days or longer and 18 years or older at the start of the given month. Mean IV iron dose was calculated as the average dose of IV iron (iron sucrose and ferrous gluconate) a patient received, among patients receiving iron during the month. This analysis was restricted to only those patients who had more than 6 sessions but less than equal to 18 sessions in a month. The permissible range of values considered for sucrose and ferrous gluconate are (50–1800mg) and (12.5–1800mg) respectively.

Categorical distribution of iron store measures, transferrin saturation (TSAT) and serum ferritin for December 2012, December 2013, and December 2014, using CROWNWeb data are shown in Figures 3.5 and 3.6, respectively, for HD patients. For PD patients, iron store measures, TSAT and serum ferritin are shown in Figures 3.11 and 3.12, respectively. For Figure 3.5, dialysis patients on treatment for ESRD at least 1 year at the time of measurement of TSAT value for that year, ≥18 years old as of December 1 of that year and who were alive through December 31 of that year are

included in the study. For each year, the latest non-missing TSAT value during October–December was used. Similar analyses were done for PD patients.

Figure 3.6 analyses include dialysis patients who were treated for ESRD for at least 1 year at the time of measurement of serum ferritin for that year, who were ≥18 years old as of December 1 of that year, and who were alive through December 31 of that year. For each year, the latest non-missing serum ferritin value during October–December, a 3-month time period, was used. Similar analyses were done for PD patients.

Percentage of all HD patients according to the number of red blood cell transfusions in a year is shown in Figure 3.7.a; calculated from Medicare claims data for years 2010–2013. Here, the denominator included all patients having a claim for at least one dialysis session during the month and who were 18 years or older at the start of the month, and the numerator consisted of the total number of claims for transfusions a patient had in a year. The modality of the first treatment in the year determines the modality of the patient for that year. Similarly, Figure 3.13.a, shows the distribution of the number of red blood cell transfusions received by PD patients, by year.

Calculations of the percentage of dialysis patients with one or more claims for a red blood cell transfusion in a given month from 2010–2013 by race are shown in Figures 3.7.b (HD patients) and 3.13.b (PD patients). For this calculation, the numerator consisted of dialysis patients with one or more red blood cell transfusion claims in a given month (the transfusion eventsclaims were identified using the codes as listed in Table m.1); the denominator included all patients having a claim for at least one dialysis session during the month and who were 18 years or older at the start of the month.

vol 2 **Table m.1 Transfusion codes used in defining a red blood cell transfusion**

Code	Code Type	Code Description
36430	CPT	Transfusion, blood or blood components
P9010	HCPCS	Blood (whole), for transfusion, per unit
P9011	HCPCS	Blood, split unit
P9016	HCPCS	Red blood cells, leukocytes reduced, each unit
P9021	HCPCS	Red blood cells, each unit
P9022	HCPCS	Red blood cells, washed, each unit
P9038	HCPCS	Red blood cells, irradiated, each unit
P9039	HCPCS	Red blood cells, deglycerolized, each unit
P9040	HCPCS	Red blood cells, leukocytes reduced, irradiated, each unit
P9051	HCPCS	Whole blood or red blood cells, leukocytes reduced, cmv-negative, each unit
P9054	HCPCS	Whole blood or red blood cells, leukocytes reduced, frozen, deglycerol, washed, each unit
P9056	HCPCS	Whole blood, leukocytes reduced, irradiated, each unit
P9057	HCPCS	Red blood cells, frozen/deglycerolized/ washed, leukocytes reduced, irradiated, each unit
P9058	HCPCS	Red blood cells, leukocytes reduced, cmv-negative, irradiated, each unit
99.03	ICD9	Other transfusion of whole blood; transfusion: blood NOS, hemodilution, NOS
99.04	ICD9	Transfusion of packed cells

Mineral and Bone Disorder

Distributions of calcium levels for HD and PD patients for December 2012, December 2013, and December 2014 using CROWNWeb data are shown in in Figures 3.14 and 3.15. Figure 3.14 analyses include HD patients on treatment for ESRD at least 1 year at the time of measurement of serum calcium value for that year, who were ≥18 years old as of December 1 of that year, and who were alive through December 31 of that year. Similar analyses were done for PD patients in Figure 3.15.

Distributions of phosphorus levels for HD and PD patients for December 2012, December 2013, and December 2014 using CROWNWeb data are shown in in Figures 3.16 and 3.17. For Figure 3.16 analyses include HD patients on treatment for ESRD at least 1 year at the time of measurement of serum phosphorus value for that year, who were ≥18 years old as of December 1 of that year, and who were alive through December 31 of that year. Similar analyses were done for PD patients in Figure 3.17.

Preventive Care

Figure 3.18 presents data on diabetic preventive care. The ESRD population includes patients initiating therapy at least 90 days prior to January 1 of the first year of each study period and with DM in the first year. Testing is tracked in the second year of each study period, and tests are at least 30 days apart. ESRD patients without Medicare inpatient/outpatient and physician/supplier coverage during the entire study period are omitted, as are general Medicare patients enrolled in an HMO or diagnosed with ESRD during the study period. Also omitted are those who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories; who have a missing date of birth; who do not survive the entire reporting period; who have ESRD for fewer than 90 days prior to the start of the reporting interval; or who are lost to follow-up during the study period. Age is calculated at the end of the study period.

Patients are defined as having DM either through medical claims (one inpatient/home health/SNF claim, or two outpatient or physician/supplier claims), or through a listing of DM on the Medical Evidence form as the primary cause of ESRD or as a comorbid condition. ICD-9-CM diagnosis codes used to define DM are 250.xx, 357.2, 362.0x, and 366.41. Methods and codes used to determine rates of HgbA1c testing and eye examinations are taken from HEDIS 2008 specifications. CPT codes 83036 and 83037 are used to identify HgbA1c testing. Codes used to identify diabetic eye examinations are as follows: CPT codes, 67028, 67030, 67031, 67036, 67038, 67039, 67040, 67041, 67042, 67043, 67101, 67105, 67107, 67108, 67110, 67112, "67113, 67121, 67141, 67145, 67208, 67210, 67218, 67220, 67221, 67227, 67228, 92002, 92004, 92012, 92014, 92018, 92019, 92225, 92226, 92230, 92235, 92240, 92250, 92260, S0620, S0621, S0625, S3000; ICD-9-CM procedure codes, 14.1–14.5, 14.9, 95.02, 95.03, 95.04, 95.11, 95.12, and 95.16; and ICD-9-CM diagnosis code V72.0. Lipid testing is identified through CPT codes 80061, 82465, 82470, 83695, 83700, 83701, 83704, 83705, 83715, 83716, 83717, 83718, 83719, 83720, 83721, 84478. Comprehensive diabetic care includes at least one HgbA1c test, at least one lipids test, and at least one eye exam. HgbA1c and lipid tests occur at least 30 days apart.

Figures 3.19 (a–d) present data on influenza vaccinations for prevalent ESRD patients by overall claims, age, race/ethnicity, and modality. The cohort for influenza vaccinations includes all ESRD patients

initiating therapy at least 90 days prior to August 1 of the first year of the study period and alive on April 30 of the second year. Patients without Medicare inpatient/outpatient and physician/supplier coverage during the study period are omitted, as are those who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories. Also omitted are those who have a missing date of birth; who have ESRD for fewer than 90 days prior to the start of the study period; or who are lost-to-follow-up during the study period. Age is calculated at the end of the study period. Influenza vaccinations are tracked between August 1 of the first year and April 30 of the second year in the study period. Influenza vaccinations are identified by CPT codes 90724, 90657, 90658, 90659, and 90660, and HCPCS code G0008.

CHAPTER 4: VASCULAR ACCESS

Data for Figures 4.1–4.3 and 4.7, and Tables 4.1 and 4.6 are obtained from the Medical Evidence form (CMS 2728); data are restricted to the most recent version. Patients with missing vascular access data are excluded.

Figure 4.1 presents data for patients who began dialysis from 2005–2013; Table 4.1 and Figures 4.2–4.3 present data for patients beginning dialysis in 2013. Age is calculated as of the date regular chronic dialysis began. Figures 4.2–4.3 exclude patients not living in the 50 states or the District of Columbia; Figure 4.7 and Tables 4.3–4.5 include a cross-section of patients alive at each time point.

Vascular access use among prevalent patients is described in Table 4.2 and Figures 4.4–4.6. For Table 4.2, CROWNWeb data is used to obtain vascular access use for December 2013. Catheter use implied any catheter use, whereas, arteriovenous (AV) fistula and AV graft use shown are without the use of a central venous catheter. Figure 4.6 has data as reported from Fistula First from July 2003 to April 2012 and CROWNWeb data from June 2012 to December 2013. May 2012 was not included in the analysis to denote the breakpoint between two sources. This figure shows prevalence of the vascular type used and for June 2012 to December 2013, the denominator is obtained from the treatment history file, limited to hemodialysis patients who are non –transplanted and are alive at the end of each month. The numerator is obtained from vascular access extract files in CROWNWeb. Vascular access use for December 2014 was obtained from CROWNWeb data for December 2014. Catheter use at

vascular access initiation includes data obtained from the Medical Evidence form for patients beginning dialysis between January 1, 2013 and December 31, 2013; vascular access data for all other time points are obtained from CROWNWeb. There is a 15-day look-back and 15-day look-forward time period to determine vascular access.

Table 4.7 and Figure 4.8 include patients with a fistula placed at any point between January 1, 2013 and December 31, 2013 who are already on ESRD at time of placement. Fistula placement was identified through inpatient, outpatient, and physician/supplier Medicare claims using the following ICD-9 procedure codes: 36818, 36819, 36820, 36821 and 36825. Subsequent first use of the placed fistula was determined by finding evidence of fistula use in CROWNWeb through the end of 2014. If the fistula was indicated to be used in CROWNWeb following the placement (and prior to any later fistula placements), the fistula was considered to have successfully matured for use. If CROWNWeb did not indicate the fistula was used following placement, the fistula was assumed to have failed to mature. In order to be included in the analyses, patients were required to have vascular access use data in CROWNWeb following the fistula placement. Time to maturation was determined using the date of fistula placement and the date of first use in CROWNWeb, given that the exact time of 'fistula maturity' is currently not determinable from CROWNWeb. Patients that died following the fistula placement were also included in the analysis.

CHAPTER 5: HOSPITALIZATION

Methods used to examine hospitalization in prevalent patients generally echo those used for the tables in *Reference Section G: Morbidity and Hospitalization* (described below). Inclusion and exclusion criteria are generally the same, as are the methods for counting hospital admissions and days, and defining the follow-up time at risk. One difference is the exclusion in Section G of patients of races that are unknown or other than White, Black/African American, Native American, or Asian; these patients are included in the Chapter 5 figures. Included patients have Medicare as primary payer, with Parts A and B coverage at the start of follow-up, and without HMO coverage. Rates include total admissions or hospital days during the time at risk, divided by patient years at risk. The period at risk begins at the later date of either January 1 or day 91 of ESRD, and censoring occurs at death,

end of Medicare Parts A and B coverage, or December 31, in addition to other censoring criteria which vary by modality as described below. Since a currently hospitalized patient is not at risk for admission, hospital days are subtracted from the time at risk for hospital admissions. Additionally, rehospitalization rates include the percentage of live hospital discharges that are followed by a subsequent hospital admission within 30 days. Hospitalization data do not exclude inpatient stays for the purpose of rehabilitation therapy.

Inpatient institutional claims are used for the analyses, and methods for cleaning claims follow those described for Section G. Adjusted rates are calculated using the model-based adjustment method on the observed category-specific rates. Predicted rates are calculated with a Poisson model, and adjusted rates are then computed with the direct adjustment method and a reference cohort. This method is described further in the discussion of Section G, and in the statistical methods section later in this chapter.

Methods in Figures 5.1–5.2 follow those for *Reference Section G: Morbidity and Hospitalization*. Figure 5.1 presents adjusted rates of total hospital admissions and days per patient year. Prevalent ESRD patients are included, and rates are adjusted for age, sex, race, and primary cause of ESRD, with the 2011 ESRD cohort used as the reference.

Figure 5.2 shows the admission rates since 2005 for period prevalent ESRD patients. Included patients have Medicare as primary payer and are residents of the 50 states, the District of Columbia, Puerto Rico, and the U.S. territories. Patients with AIDS as a primary or secondary cause of death are excluded, as are patients with missing age or sex information. Rates are adjusted for age, sex, race, and primary cause of ESRD using the model-based adjustment method. The reference cohort includes period prevalent ESRD patients in 2011. New dialysis access codes for PD patients appeared in late 1998. For PD patients, dialysis access hospitalizations are those defined as "pure" inpatient vascular/dialysis access events, as described for Tables G.11–G.15. For HD patients, vascular access hospitalizations include "pure" inpatient vascular access events, and vascular access for HD patients excludes codes specific to PD catheters (996.56, 996.68, and V56.2). Principal ICD-9-CM diagnosis codes are used to identify cardiovascular and infection admissions. The cardiovascular category consists of codes 276.6, 394–398.99, 401–405, 410–420,

421.9, 422.90, 422.99, 423–438, and 440–459, while infection is indicated by codes 001–139, 254.1, 320–326, 331.81, 372–372.39, 373.0–373.2, 382–382.4, 383, 386.33, 386.35, 388.60, 390–393, 421–421.1, 422.0, 422.91–422.93, 460–466, 472–474.0, 475–476.1, 478.21–478.24, 478.29, 480–490, 491.1, 494, 510–511, 513.0, 518.6, 519.01, 522.5, 522.7, 527.3, 528.3, 540–542, 566–567.9, 569.5, 572–572.1, 573.1–573.3, 575–575.12, 590–590.9, 595–595.4, 597–597.89, 598.0, 599.0, 601–601.9, 604–604.9, 607.1, 607.2, 608.0, 608.4, 611.0, 614–616.1, 616.3–616.4, 616.8, 670, 680–686.9, 706.0, 711–711.9, 730–730.3, 730.8–730.9, 790.7–790.8, 996.60–996.69, 997.62, 998.5, and 999.3.

Figure 5.3 shows adjusted infectious and cardiovascular hospital day rates among prevalent ESRD patients. Again, rates are adjusted for age, gender, race, and primary cause of ESRD, with ESRD patients in 2011 used as the reference cohort. Principal ICD-9-CM codes for cardiovascular and infection hospitalizations are listed in the discussion of Figure 5.2.

Table 5.1 presents unadjusted and adjusted admission rates among adult (aged 22 and older) period prevalent HD patients. Principal ICD-9-CM diagnosis codes are used to identify cause-specific admissions: codes for cardiovascular and infectious admissions are listed in the discussion of Figure 5.2, while codes for vascular access infection are listed in Table m.2 in the section describing the methods for *Reference Section G: Morbidity and Hospitalization*. Rates are adjusted for age, sex, race, and primary ESRD diagnosis; values presented by one factor are adjusted for the other three. For adjusted rates, HD patients in 2011 are used as the reference cohort. Values by age, sex, race, and primary cause of ESRD are shown for 2012–2013 prevalent HD patients.

Figures 5.4–5.10 show rates of rehospitalization and/or death among prevalent HD patients of all ages (aged 66 and older in Figure 5.4), 30 days after hospital discharge. Live hospital discharges from January 1 to December 1 of the year are identified as index hospitalizations; the latter date provides a 30-day period following the latest discharge to evaluate rehospitalization. The units of analyses include hospital discharges rather than patients. Hospitalization data exclude transfers. Discharges with a same-day admission to long-term care or a critical access hospital are excluded. For HD patients in Figures 5.5–5.10, discharges with a transplant, loss to follow-up, or end of payer status before day 30 after discharge are excluded. For ESRD patients in Figure

5.4, the same exclusions apply except as related to transplant; discharges from transplant patients are excluded if they occur after 2 years and 11 months following the most recent transplant to ensure that complete claims are available during the 30-day post-discharge period.

Figures 5.4–5.7 and 5.9–5.10 indicate the percentage of discharges with readmission and/or death within 30 days after discharge. The groups indicate status at day 30 after discharge from the index hospitalization, and do not consider events after day 30. Figures 5.5–5.6 include all-cause index hospitalizations, while in Figure 5.7, categories of cause-specific admissions are based on principal ICD-9-CM diagnosis codes of the index hospitalization. Codes for cardiovascular and infectious hospitalizations are listed in the discussion of Figure 5.2; vascular access infection codes are 996.62 and 999.31. Figures 5.9–5.10 include the codes for discharges from cardiovascular hospitalizations listed for Figure 5.2, and Figure 5.10 includes the codes for acute myocardial infarction (AMI), congestive heart failure (CHF), stroke and dysrhythmia. ICD-9 CM codes for AMI: 410.x0 and 410.x1; CHF: 398.91, 402.x1, 404.x1, 404.x3. 425, and 428; stroke: 430–434; and dysrhythmia: 426–427. Figure 5.8 indicates the percentage of hospital discharges followed by a 30-day rehospitalization by cause-specific groups for both the index hospitalization and the rehospitalization. Categories of cause-specific rehospitalization also include non-vascular access infections, defined by infection codes excluding 996.62 and 999.31, and other, defined by codes other than cardiovascular and infectious.

Figure 5.4 shows overall percentages of discharges with 30-day rehospitalization and/or death in the general Medicare, chronic kidney disease (CKD), and ESRD populations. Data include point prevalent Medicare patients on December 31, 2012, who are aged 66 and older. For general Medicare patients with and without CKD, CKD is defined during 2012, and patients remain who are without ESRD, with continuous enrollment in Medicare Parts A and B, and without HMO coverage. Live hospital discharges from January 1 to December 1, 2013 are included.

Chapter 6: Mortality

Unless otherwise specified, patient cohorts underlying the analyses presented in Chapter 6 include Medicare and non–Medicare patients living in the 50 states, the District of Columbia, Puerto Rico, and the U.S. territories.

Figure 6.1 shows trends in mortality rates by modality among incident ESRD patients during 1996–2013. Modalities include ESRD, dialysis, HD, CAPD/CCPD, and first transplant; results aggregating across modalities are also presented. Patients are classified by year based on date of ESRD onset. Dialysis patients are followed from ESRD onset (i.e., day one) censored at the earliest of date of transplant, loss to follow-up, recovery of native renal function, or December 31, 2013. Transplant patients begin follow-up at the date of transplant and are censored on December 31, 2013. Adjusted mortality rates for each period after first treatment are computed separately by taking an appropriate weighted average of Cox-regression based predicted rates. The adjustment is made through model-based direct standardization, and is described later in the *Statistical Methods* section of this chapter. The Cox proportional hazard model serves as the basis for the predicted rates, adjusted for age, sex, race, and primary cause of ESRD. The reference population consists of 2011 period prevalent ESRD patients.

Figure 6.2 shows adjusted all-cause mortality among incident patients by year after incidence. The rates are based on the predicted cumulative hazard for patients in the reference dataset from an adjusted Cox model on survival based on incident patients in 2012.

Figure 6.3 displays adjusted mortality for incident patients in the first year by modality. Patients are followed from ESRD onset (day one; as reflected by first service date) up to one year, and censored at loss to follow-up, transplant, or recovery of kidney function. Note that patients with unknown age, sex, or primary cause of ESRD are excluded from the analysis. Rates are adjusted for age, sex, race, Hispanic ethnicity, and primary cause of ESRD, with the 2011 incident ESRD patients serving as the reference population. The adjustment method is similar to that used for Figure 6.2.

Table 6.1 shows the death rates for different race and age categories among period prevalent transplant and dialysis patients in 2012. Adjusted death rates within each age and race category are determined by calculating the weighted average within each sex and diagnosis category within each age and race category. Weighting is calculated according to the age, race, sex, and diagnosis category prevalence within the 2011 period prevalent reference data.

Table 6.2 shows cause-specific mortality rates by modality, and, among all ESRD patients, by age, race,

and sex. Rates are adjusted for age, race, sex, ethnicity, and primary cause of ESRD in a manner similar to that used in Table 6.1. Rates for each demographic group are adjusted for all factors except the given group; e.g., death rates by age are adjusted for race, sex, ethnicity, and primary cause of ESRD, not age.

Table 6.3 presents adjusted three-month, one-year, two-year, three-year, and five-year survival by modality, and, in the ESRD cohort, by age, sex, race, and primary cause of ESRD. Data are obtained from Reference Tables in *Reference Section I: Patient Survival*.

Table 6.4 presents expected remaining lifetimes in years for the 2012 general U.S. population, and for 2013 prevalent dialysis and transplant patients. For period prevalent ESRD patients in 2013, expected lifetimes are calculated using the death rates from a generalized linear mixed model with 16 age groups, assuming a constant mortality rate within each age group. The method for calculating expected remaining lifetimes is described in the *Statistical Methods* section at the end of this chapter. Data for the general population are obtained from the CDC's National Vital Statistics Report, Table 7, "Life expectancy at selected ages, by race, Hispanic origin, race for non-Hispanic population, and sex: United States, 2012."

Table 6.5 shows adjusted all-cause mortality in the ESRD and general Medicare populations (over the age of 65) using the Medicare 5 percent sample. Follow-up for ESRD patents is from January 1 to December 31 of each year. For general Medicare patients, follow-up is from January 1 to December 31 of each year, censored at ESRD and at the end of Medicare entitlement. Adjusted mortality is adjusted for age, sex, and race, with 2011 ESRD patients serving as the reference.

Table 6.6 presents both unadjusted and adjusted all-cause mortality in the ESRD, dialysis, transplant, and general Medicare patients with cancer, DM, CHF, cerebrovascular accident/transient ischemic attack (CVA/TIA), and AMI. All cohorts are defined on January 1, and include patients aged 65 and older. Adjustment methods and follow-up are as defined for Table 6.5.

Chapter 7: Transplantation

Introduction

Figures 7.1–7.4 present an overview of trends in kidney transplantation. Figure 7.1 juxtaposes the percentage of prevalent dialysis patients wait-listed for a kidney transplant with the falling rate of transplantation in dialysis patients at all ages, 1996–2013. The data source is Reference Tables E.4 and E.9. Figure 7.2 shows the number of ESRD-certified candidates on the OPTN kidney transplant waiting list on December 31 of each year, for first and subsequent kidney-alone or kidney plus other organ transplants. Figure 7.2 also shows the median waiting time from wait-listing to kidney transplantation for candidates for kidney-alone transplants (i.e., the time by which 50% of these candidates had received a kidney transplant). Candidates listed at more than one transplant center on December 31 are counted only once. Median waiting time is reported for candidates newly listed in each given year. The data source is Reference Tables E.2 and E.3. Figure 7.3 presents the number of transplants by donor type. The data source is Reference Tables E.8, E.8.2, and E.8.3. Figure 7.4 shows the cumulative number of functioning kidney-alone and kidney-pancreas transplants. The data source is Reference Table D.9.

Waiting List

Figure 7.5 shows the percentage of patients wait-listed or receiving a deceased or living donor kidney-alone or kidney plus other organ transplant within one year of ESRD initiation, stratified by age. The data source is Reference Table E.5.2.

Figure 7.6 shows the annual mortality rates of dialysis patients who were wait-listed for a kidney-alone or kidney plus other organ transplant, per 1,000 dialysis patient years at risk, by time since listing. The data source is Reference Table H.6.

Transplant Counts and Rates

Table 7.1 shows the unadjusted kidney transplant rates of all donor types, by age, sex, race, and primary cause of ESRD, per 100 dialysis patient years. The data source is Reference Table E.9.

Figures 7.7–7.10 illustrate the counts and unadjusted rates of deceased kidney-alone and simultaneous kidney-pancreas transplants by age, sex, race, and primary cause of ESRD. The data source is Reference Tables E.8.2 and E.9.2.

Figures 7.11–7.14 portray the counts and unadjusted rates of living donor kidney-alone and simultaneous kidney-pancreas transplants by age, sex, race, and primary cause of ESRD. Diagnosis of cystic disease is included in the other diagnoses. The data source is Reference Tables E.8.3 and E.9.3.

Deceased Donation Counts and Rates

Figures 7.15–7.17 show the counts and unadjusted rates of deceased donor donation by age, sex, and race among all deaths among the U.S. population younger than 75 years old. Donors had at least one kidney recovered. Data on the deceased donors are obtained from United Network for Organ Sharing (UNOS), and data on the annual number of deaths in the U.S. population are obtained from the Centers for Disease Control and Prevention.

Transplant Outcomes

Table 7.2 shows one-, five-, and ten-year graft and patient outcomes for recipients who received a first kidney transplant from a deceased donor. Data sources for one-, five-, and ten-year trends are Reference Tables F.2, F.14, I.26; F.5, F.17, I.29; and F.6, F.18, I.30, respectively.

Table 7.3 shows one-, five-, and ten-year graft and patient outcomes for recipients who received a first kidney transplant from a living donor. Data sources for one-, five-, and ten-year trends are Reference Tables F.8, F.20, I.32; F.11, F.23,I.35; and F.12, F.24, I.36, respectively.

In both Tables 7.2 and 7.3, data are reported as unadjusted probabilities of each outcome, computed using Kaplan-Meier methods. All-cause graft failure includes repeat transplantation, return to dialysis, and death. The death outcome is not censored at graft failure, and deaths that occur after repeat transplantation or return to dialysis are assigned to the transplant cohort.

Figure 7.18 presents the percentage of acute rejections reported during the first post-transplant year in adult, first-time, kidney-alone transplant patients after discharge from the initial transplant hospitalization with a functioning graft. A recipient is assumed to have acute rejection if OPTN data collection forms note (1) acute rejection episodes, (2) that medications were given for acute rejection, or (3) that acute rejection was the primary cause of graft failure. If multiple rejection episodes are reported during the first year, only one rejection is counted in the numerator.

Table 7.4 presents the post-transplant total hospital admission rates, by age, sex, race, ethnicity, and primary cause of ESRD, per 1,000 patient years, among all kidney transplant patients. The data source is Reference Table G.5.

Chapter 8: Pediatric ESRD

Information on pediatric patients is a subset of ESRD patient data reported in other chapters of the ADR; methods used for most figures are therefore the same as those described in the related chapter discussions.

After reviewing the height and weight of patients aged 0–4 years old from 1996–2013, from the Medical Evidence form, a data cleaning process was deemed necessary for the pediatric chapter. There were 189 patients with unreasonable height and weight values, which we considered to be adults mistaken as pediatric patients. These patients have been excluded from all special analyses in the pediatric chapter.

Hospitalization

Figures 8.3–8.5 present adjusted admission rates in the first year of ESRD, by age, and modality, for 2003–2007 and 2008–2012 incident patients younger than 22. The patients are divided into five age groups (ages 0–4, 5–9, 10–13, 14–17 and 18–21) or three modality groups (HD, PD, and transplant). Since in-center hemodialysis patients who are younger than 65 and not disabled cannot bill for hospitalizations until 90 days after ESRD initiation, the 90-day rule is applied. Patients are required to survive the first 90 days after initiation, and are followed for admissions for up to one year after day 90. Data cleaning and counting of admissions and time at risk for admissions generally follow methods described for *Reference Section G: Morbidity and Hospitalization*. Censoring occurs at death, loss to follow-up, end of payer status, December 31, 2013, or at one year. Censoring also occurs three days prior to transplant for dialysis patients, and three years after the transplant date for transplant patients. Rates are adjusted for sex, race, Hispanic ethnicity, and primary cause of ESRD. Adjusted rates are calculated with a model-based adjustment method and an interval Poisson model. The reference cohort includes incident ESRD patients aged 0–21 years in 2010–2011. Principal ICD-9-CM diagnosis codes used for cardiovascular and infectious hospitalizations are listed in the discussion of Figure 5.1.

Mortality and Survival

Figures 8.6–8.8 present adjusted all-cause and cause-specific mortality in the first months of ESRD, by age, modality, and ethnicity, for 2003–2007 and 2008–2012 incident patients younger than 22 years old. The patients are divided into five age groups (ages 0–4, 5–9, 10–13, 14–17 and 18–21) or three modality groups (HD,

PD, and transplant). Dialysis patients are followed from the day of ESRD onset until December 31, 2013, and censored at loss to follow-up, transplantation, or recovered function. Transplant patients who receive a first transplant in a calendar year are followed from the transplant date to December 31, 2013. Rates by age are adjusted for sex, race, Hispanic ethnicity, and primary cause of ESRD; rates by modality are adjusted for age, sex, race, Hispanic ethnicity, and primary cause of ESRD. Incident ESRD patients who were younger than 22 years in 2010–2011 are used as the reference cohort. Cardiovascular mortality is defined using codes from past and current Death Notification forms: 01, 02, 03, 04, 1, 2, 3, 4, 23, 25, 26, 27, 28, 29, 30, 31, 32, 36, and 37; Infection mortality is defined using codes from past and current Death Notification forms: 10, 11, 12, 13, 33, 34, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 70, 71,74.

Figure 8.9 presents five-year survival for 2004–2008 incident ESRD patients aged 0–21 years, by age, modality, and ethnicity. The patients are divided into five age groups (age 0–4, 5–9, 10–13, 14–17 and 18–21) or three modality groups (HD, PD, and transplant). Dialysis patients are followed from the day of ESRD onset until December 31, 2013, and censored at loss to follow-up, transplantation, or recovered kidney function. Transplant patients who receive a first transplant in a calendar year are followed from the transplant date until December 31, 2013. Probabilities by age are adjusted for sex, race, Hispanic ethnicity, and primary cause of ESRD; probabilities by modality are adjusted for age, sex, race, Hispanic ethnicity, and primary cause of ESRD. The reference population consists of 2010–2011 incident pediatric ESRD patients.

Vascular Access

Data for Figures 8.10–8.12 and Table 8.2 are obtained from the Medical Evidence form; data are restricted to the most recent version. Figures 8.11 and 8.12 also include data from CROWNWeb. Patients with missing vascular access data are excluded. Figure 8.10 and Table 8.2 present data for pediatric patients who began dialysis from 2006–2013; age is calculated as of the date regular chronic dialysis began. In Figure 8.11, all HD pediatric patients who had ESRD at least 90 days at the time vascular access was reported were included. Patients must have been alive as of December 31, 2014. Figure 8.12 presents vascular access use during the first year of HD by time since initiation of ESRD treatment.

Vascular access at initiation includes data obtained from the Medical Evidence form among pediatric patients new to HD from 06/01/2012–12/31/2012. The same patient cohort was followed for a year. Vascular access data for all other time points are obtained from CROWNWeb, and transitions to transplant/PD/death/other are obtained from the RXHIST (treatment history) file. For the 1-month, 3-month, 6-month, 9-month and 1-year time points, there is a 30 day look-back and look-forward time period to determine vascular access at that time point.

Transplantation

Figure 8.13 presents an overview of the pediatric transplant population. Figure 8.13.a shows the rate of ESRD among the U.S. population 0–21 years old, and the rate of transplantation in dialysis patients aged 0–21 years at transplant, 1996–2013. Pre-emptive transplant patients were included in both the numerator and the denominator. Figure 8.13.b shows the number of ESRD-certified pediatric candidates (0–21 years old) on the OPTN kidney transplant waiting list on December 31 of each year, and the median waiting time from wait-listing to kidney transplantation for new candidates (i.e., the time by which 50% of newly wait-listed candidates had received a kidney transplant). Candidates listed at more than one center on December 31 are counted only once. Median waiting time is reported for patients listed in each given year. Figure 8.13.c presents transplant counts for all pediatric (0–21 years old) recipients, by donor type.

Transplant and Outcomes

Figure 8.14 presents transplant rates per 100 dialysis patient years among pediatric patients on dialysis (0–21 years old). Figure 8.14.a presents rates by age group. Figure 8.14.b presents rates by race. Asian and Native American group were not displayed because of the fluctuation due to small population. Rates were calculated among dialysis patient years in that specific subgroup.

Figure 8.15 shows the median waiting time from initiation of HD or PD in incident pediatric ESRD patients (0–21 years old) to first transplant. Patient age in Figure 8.15.b was defined as the age at initiation of HD or PD. Incident dialysis and transplant patients are defined at the onset of dialysis or the day of transplant with the 60-day rule. Figure 8.15.b includes pediatric

patients (0–21 years old) starting initiation of HD or PD in 1996–2012, and having the first transplant before 12/31/2014.

Figure 8.16 presents the repeat transplant rate for all pediatric patients (0–21 years old). The study cohort is 1996–2013. Figure 8.16.a shows the rates by age at the first transplant date, Figure 8.16.b presents the rates by the primary cause of ESRD. When calculating the rates, the numerator includes the total number of renal re-transplants, and the denominator includes the total number of renal transplants. Figure 8.16b includes only patients who are 0–21 years old at the time of first transplant and repeat transplant.

Table 8.3 presents patient outcomes for pediatric recipients (ages 0–21) who received a kidney transplant from a deceased or living donor. Table 8.3.a presents adjusted one-year outcomes, Table 8.3.b presents adjusted five-year outcomes, and Table 8.3.c presents adjusted ten-year outcomes. Death outcome probabilities are calculated among first-time transplants. Data are reported as adjusted probabilities of each outcome, and are computed using Cox proportional hazards models. The death outcome is not censored at graft failure, and includes deaths that occur after repeat transplantation or return to dialysis. These probabilities are adjusted as described below.

For the all-cause graft failure analyses, data are reported as adjusted probabilities of each outcome, and are computed using Cox proportional hazards models. Probabilities are adjusted for age, sex, race, primary cause of ESRD, and first versus subsequent transplant, and standardized to 2011 patient characteristics. All-cause graft failure includes re-transplant, return to dialysis, and death.

For the probability of death analyses, the Cox model and the model-based adjustment method are used for adjusted probabilities. The adjusted survival probability for a cohort is based on expected survival probability for the cohort and the reference population. The survival/conditional probabilities are modeled separately for each period: 0–90 days, 91 days to one year, one year to two years, two years to three years, three years to five years, and five years to ten years. The expected survival probabilities for 90 days, one year, two years, and so on are calculated based on the survival/conditional survival probabilities. We fit one model for each cohort to obtain adjusted

probabilities overall and for age, sex, race, and primary cause of ESRD. The reference population consists of 2011 incident ESRD patients. The death outcome is not censored at graft failure, and includes deaths that occur after re-transplant or return to dialysis.

Young Adults

Analytical methods in the young adult section are similar to the pediatric section. The reference population consists of 2010–2011 incident young adult ESRD patients who were 22–29 years old.

Chapter 9: Cardiovascular Disease

This chapter describes the prevalence of cardiovascular comorbidities and selected cardiovascular procedures in fee-for-service, eligible Medicare enrollees. According to a previously validated method for using Medicare claims to identify diabetic patients, a patient is considered diabetic if, within a one-year observation period, he or she has a qualifying ICD-9-CM diagnosis code of diabetes mellitus (DM) on one or more Part A institutional claims (inpatient, skilled nursing facility, or home health agency), or two or more institutional outpatient claims and/or Part B physician/supplier claims (Herbert et al., 1999). With this methodology, we identify patients with comorbid conditions and procedures using the ICD-9-CM diagnosis codes.

Cardiovascular comorbidities include atherosclerotic heart disease (ASHD), acute myocardial infarction (AMI), congestive heart failure (CHF), cerebrovascular accident/transient ischemic attack (CVA/TIA), peripheral arterial disease (PAD), atrial fibrillation (AFIB), and sudden cardiac arrest and ventricular arrhythmias (SCA/VA). The algorithm above is used to define these cardiovascular conditions using the following ICD-9-CM code values in Table m.2.

vol 2 Table m.2 ICD-9-CM diagnosis codes used to define cardiovascular disorders in the USRDS ADR, Volume 2, Chapter 9

Condition name	ICD-9-CM diagnosis codes
Any cardiovascular disease (CVD)	398.91; 402.01, 402.11, 402.91; 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; 410-414; 422; 425-428; 430-438; 440-444; 447; 451-453; 557; V42.1, V45.0, V45.81, V45.82, V53.3
Atherosclerotic heart disease (ASHD)	410-414; V45.81, V45.82
Acute myocardial infarction (AMI)	410; 412
Congestive heart failure (CHF)	398.91; 402.01, 402.11, 402.91; 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; 422a; 425a; 428; V42.1a
Systolic or both systolic & diastolic	428.2, 428.4
Diastolic only	428.3
Heart failure, unspecified	398.91; 402.01, 402.11, 402.91; 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; 422a; 425a; 428 (not 428.2-428.4); V42.1a
Cerebrovascular accident/transitory ischemic attack (CVA/ TIA)	430–438
Peripheral arterial disease (PAD)	440–444; 447; 557
Atrial fibrillation (AFIB)	427.3
Sudden cardiac arrest/ventricular arrhythmias (SCA/VA)	427.1, 427.4, 427.41, 427.42, 427.5, 427.69

Data Source: ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification. Diagnosis codes can have up to five digits with a decimal point between the 3rd and 4th digit. Codes listed with three digits include all existing 4th and 5th digits, and those listed with four digits include all existing 5th digits. Peripheral arterial disease is defined as having a diagnosis and/or a procedure. These codes are used to determine prevalent or comorbid CHF, but are excluded when determining incident CHF events and when CHF is the dependent variable.

Cardiovascular procedures include percutaneous coronary interventions (PCI), coronary artery bypass grafting (CABG), and the placement of implantable cardioverter defibrillators (ICD) and cardiac resynchronization devices with defibrillators (CRT-D). Procedures require only one claim with the procedure code. The presence of PAD is determined by the diagnosis or a claim for a procedure. Table m.3 shows the codes and type of claims used to identify each procedure.

Figure 9.1 shows the causes of death in prevalent dialysis patients during 2011-2013. The data source is Reference Table H.12. Table 9.1 displays the prevalence of cardiovascular comorbidities and procedures, by modality, age, race and gender, among ESRD patients in 2013. The cohort includes point prevalent hemodialysis, peritoneal dialysis, and transplant patients with Medicare as primary payer on January 1, 2011, who are continuously enrolled in Medicare Parts A and B from July, 1, 2010 to December 31, 2010, and whose ESRD service date is at least 90 days prior to January 1, 2011, and who survived past 2012. We exclude patients with unknown age, gender, or race and those with an age calculated to be less than zero or greater than 110. Figures 9.2 and 9.3 show the percentage of patients who had cardiovascular comorbidities, by modality and age, respectively, among ESRD patients in 2013. The cohort is the same one used for Table 9.1. Figure 9.4 illustrates the unadjusted survival of patients, by cardiovascular diagnosis or procedure and modality. The cohort includes point prevalent hemodialysis, peritoneal dialysis, and transplant patients with Medicare as primary payer on January 1, 2011, who are continuously enrolled in Medicare Parts A and B from July, 1, 2010 to December 31, 2010, and whose first ESRD service date is at least 90 days prior to January 1, 2011, and who survived past 2011. Patients with CHF, PAD, and CVA/TIA are those whose Medicare claims indicated the diagnosis or procedure in 2011 or Medical Evidence forms reported the comorbidities during ten years before the first ESRD service date. Patients with ASHD, AMI, AFIB, SCA/VA, PCI, CABG, or ICD/CRT-D are those whose Medicare claims indicate the diagnosis or procedure in 2011. Patients are followed from January 1, 2012, until the earliest date of death, modality change, transplant, loss to follow-up, recovery of renal function, or December 31, 2013. The Kaplan-Meier method is used to estimate all-cause survival.

Table 9.2 describes the characteristics of hemodialysis and peritoneal dialysis patients with CHF, by age, sex, race, diabetic status, and type of heart failure in 2013. The study cohort is similar to that described for Table 9.1, except that patients who received a transplant were excluded.

vol 2 Table m.3 Procedure codes (ICD-9-CM and HCPCS) & claims files used to define cardiovascular procedures in the ADR, Volume 2, Chapter 9

Peripheral arterial disease (PAD)

ICD-9-CM Procedure codes:
Claims files searched: IP, OP, SN
Values: 39.25, 39.26, 39.29; 84.0, 84.1, 84.91

HCPCS codes: Claims files searched: PB, OP-revenue Values: 24900, 24920, 25900, 25905, 25920, 25927, 27295, 27590, 27591, 27592, 27598, 27880, 27881, 27882, 27888, 27889, 28800, 28805, 34900, 35131, 35132, 35141, 35142, 35151, 35152, 34051, 34151, 34201, 34203, 34800–34834, 35081– 35103, 35331, 35341, 35351, 35355, 35361, 35363, 35371, 35372, 35381, 35450, 35452, 35454, 35456, 35459, 35470, 35471, 35472, 35473, 35474, 35480, 35481, 35482, 35483, 35485, 35490, 35491, 35492, 35493, 35495, 35521, 35531, 35533, 35541, 35546, 35548, 35549, 35551, 35556, 35558, 35563, 35565, 35566, 35571, 35583, 35585, 35587, 35621, 35623, 35646, 35647, 35651, 35654, 35656, 35661, 35663, 35665, 35666, 35671

Percutaneous coronary interventions (PCI)

ICD-9-CM Procedure codes:
Claims files searched: IP, OP, SN
Values: 00.66; 36.01, 36.02, 36.05, 36.06, 36.07

HCPCS codes: Claims files searched: PB, OP-revenue Values: 92980-92982, 92984, 92995- 92996, G0290, G0291

Coronary artery bypass graft (CABG)

ICD-9-CM Procedure codes:
Claims files searched: IP Values: 36.1

Implantable cardioverter defibrillators & cardiac resynchronization therapy with defibrillator (ICD/CRT-D)

ICD-9-CM Procedure codes:
Claims files searched: IP, OP, SN
Values: 00.51; 37.94

Data Source: ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification; HCPCS, Healthcare Common Procedure Coding System, IP, inpatient, OP, outpatient services during inpatient stay, SN, skilled nursing facility, PB, physician and supplier services covered by Part B, OP-revenue, outpatient revenue claims during inpatient stay. ICD-9-CM procedure codes have up to four digits with a decimal point between the 2nd and 3rd digits. Codes listed with three digits include all possible 4th digits. HCPCS codes have 5 digits without a decimal point. Peripheral arterial disease is defined as having a diagnosis and/or a procedure.

Chapter 10: Providers

The methods and data sources used to identify dialysis facilities are the same as those used in Reference Table J. Please refer to the section on *Reference Section J: Providers*, found later in this document, for detailed methods and data source description.

A facility's hospital-based or freestanding status is determined from the third and fourth digits of the provider number assigned to each unit by CMS. A facility's profit status is determined through the ownership type field on the CMS survey (for years prior to 2001) or the profit status field of the DFC database (2001 to the present).

Figures 10.1 and 10.2 show the counts of units and patients for all provider types from the 2011-2013 Annual Facility Survey. Figure 10.3 presents the percentage of patients who are being treated by PD and home HD by provider type and patient characteristics.

Figure 10.4 presents the percentage of patient-months

in 2013 during which a hemodialysis patient had a particular type of access: catheter, fistula, graft, or other/missing type. The figures show these percentages among all patient-months ("Among Prevalent Dialysis Patients") and only among those patient-months during which a HD patient was new to dialysis ("Among Incident Dialysis Patients") stratified by patient characteristics. Figure 10.5 shows the distribution of all facilities' percentage of patients with the above-specified vascular access types, among both incident and all prevalent hemodialysis patients.

Figure 10.6 shows the percentage of dialysis patients on the kidney transplant waiting list in 2010, 2011, 2012, and 2013, stratified by patient characteristics. This set of figures measures wait-listing only among patients younger than 70 because transplants in people aged 70 and older occur much less frequently.

Hospitalization and Mortality

Tables 10.1 and 10.4 compare mortality and

hospitalization among dialysis provider types and chains, using standardized mortality ratios (SMRs) and standardized hospitalization ratios (SHRs). Both measures are estimated using a two-stage Cox proportional hazards model (described below). SMR and SHR calculations include all 2010, 2011, 2012, and 2013 period prevalent dialysis patients; SHR calculations include only dialysis patients with Medicare as primary payer.

Adjustment

Both SMRs and SHRs are adjusted for patient age, race, ethnicity, sex, DM, duration of ESRD, nursing home status, patient comorbidities at incidence, and body mass index (BMI) at incidence. The SMR is additionally adjusted for race-specific population death rates.

To facilitate comparison of the SMR and SHR across years, Table 10.1 (SMR) and Table 10.3 (SHR) report these measures with the year adjustment removed from the model. That is, the measures do not compare outcomes for each year to the national norm for that year, but rather compare each year to the national averages over the entire reporting period combined (e.g., four years). Because all years are reported relative to the same standard, values can be compared across years, facilitating identification of short-term trends over time. Tables 10.2 (SMR) and 10.4 (SHR) present a one-year version of the respective measure.

Confidence Intervals

Given the large number of observations that go into the SMR and SHR models, we choose to approximate rather than directly calculate the 95% confidence intervals for the respective measure. This approach gains efficiency with minimal loss of precision. In particular, the exact 95% confidence intervals are derived by applying the Wilson-Hilferty Approximation (Wilson and Hilferty, 1931), which approximates chi-square percentiles using percentiles of the standard normal distribution (Breslow and Day, 1987).

Patient Placement

We identified each patient's dialysis provider at each point in time using data from a combination of Medicare-paid dialysis claims, the Medical Evidence form (CMS 2728), and paid dialysis claims. Starting with day 91 after onset of ESRD, we attribute a patient to a facility according to the following rules. A patient is attributed to a facility once the patient has been treated there for 60 days. When a patient transfers from one facility to

another, the patient continues to be attributed to the original facility for 60 days and then is attributed to the destination facility. In particular, a patient is attributed to their current facility on day 91 of ESRD if that facility had treated him or her for at least 60 days. If on day 91, the facility had treated a patient for fewer than 60 days, we wait until the patient reaches day 60 of treatment at that facility before attributing the patient to the new facility. When a patient is not treated in a single facility for a span of 60 days (for instance, if there were two switches within 60 days of each other), we do not attribute that patient to any facility. Patients were censored upon receiving a transplant. Patients who withdrew from dialysis or recovered renal function remained assigned to their treatment facility for 60 days after withdrawal or recovery. If a period of one year passed with neither paid dialysis claims nor CROWNWeb/SIMS information to indicate that a patient was receiving dialysis treatment, we considered the patient lost to follow-up and did not include that patient in the analysis from that point forward. When dialysis claims or other evidence of dialysis reappeared, the patient was included in the analysis again starting after 60 days of continuous therapy at a single facility.

Chapter 11: Medicare Expenditures for Persons With ESRD

For the 2015 ADR, reported costs of ESRD include only those ESRD beneficiaries covered by Original Medicare (fee-for-service) for their Medicare Part A and B benefits. Medicare expenditures can be calculated from the claims submitted for payment for health care provided to these individuals, but not for those enrolled in Medicare Advantage (managed care) plans. The Medicare program pays for services provided through Medicare Advantage plans on a risk-adjusted, per-capita basis, and not by specific claims for services. Methods of estimating Medicare expenditures for Medicare Advantage beneficiaries with ESRD will be explored for future ADRs.

Figures 11.1–11.2, total costs to Medicare, were taken from Reference Table K.1. In Figure 11.2 total Medicare from each year costs was taken from the Medicare Trustees Report, Table B.1 which is available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/TrusteesReports.html*. Part C costs were deducted to show the fee-for-service Medicare costs. Figure 11.3 presents point prevalence of Medicare as Primary Payer, Medicare as Secondary Payer, and non-Medicare ESRD patients by year using the USRDS database. Figure 11.4 describes the

percent change in ESRD Medicare spending in total and per patient year, excluding claims with Medicare as secondary payer. The calculations are based on Reference Table K.4. Figure 11.5 shows the total Medicare ESRD expenditures by type of service, which was taken from Reference Table K.1. The analysis includes period prevalent patients, specifically, all ESRD patients with at least one Medicare claim. Figure 11.6 describes total Medicare ESRD expenditures by modality. Medicare costs are from claims data. Figure 11.7 shows the total Medicare ESRD expenditures per person per year by modality. The analysis includes period prevalent ESRD patients, and excludes patients with Medicare as secondary payer. Data sources are Reference Tables K.7, K.8, K.9.

Chapter 12: Prescription Drug Coverage in Patients With ESRD

In figures and tables regarding enrollment and utilization of Medicare Part D, we analyze cohorts of Medicare enrollees in 2011–2013 based on 100% of the ESRD population receiving hemodialysis, receiving peritoneal dialysis, or with a functioning kidney transplant, along with cohorts of Medicare enrollees in 2011–2013 based on the Medicare 5 percent sample (general Medicare enrollees). For general Medicare enrollees, we require continuous enrollment in Medicare Parts A and B during the previous calendar year; and Medicare enrollment in January of the index year. For hemodialysis, peritoneal dialysis, and kidney transplant cohorts, we identify all point prevalent patients alive and enrolled in Medicare on January 1 of the index year, with ESRD onset at least 90 days earlier; treatment modality is identified on January 1.

In Figures 12.1–12.3, the type of prescription drug coverage is defined sequentially. That is, we first classify patients as "Part D with LIS," if there exists at least one calendar month in 2013 with Part D enrollment and receipt of the low-income subsidy (LIS). In patients without one such month, we classify remaining patients as "Part D without LIS," if there exists at least one calendar month with Part D enrollment. In patients without one such month, we classify remaining patients as "retiree drug subsidy," if there exists at least one calendar month with employer receipt of the subsidy. In patients without one such month, we classify remaining patients as "other creditable coverage," if there exists at least one calendar month with enrollment in military, government employee, or employer group health

plans. And we classify all remaining patients as "no known coverage."

For Figure 12.4 and Table 12.1, we classify Part D enrollees as LIS recipients, if there exists at least one calendar month in 2013 with receipt of the LIS. In Table 12.3, the proportion enrolled in Part D is the sum of those enrolled in Part D with the LIS and without the LIS.

Part D costs for ESRD patients are based on Part D enrollees with traditional Medicare (Parts A&B), using the period prevalent, as-treated model. ESRD patients in Medicare Advantage Part D plans and Medicare secondary payer are excluded. In an as-treated model, patients are first classified by their modality at entry into the analysis, and retain that classification until a modality change. When a change is encountered in the data, the beginning modality is censored at the change date plus 60 days, and a new observation with the new modality is created. The first 60 days after a change are attributed to the previous modality to account for any carryover effects. Some figures also include the general Medicare population (not enrolled in a Medicare Advantage Part D plan) based on the Medicare 5 percent sample. Costs in Tables 12.4–12.6 and Figure 12.5 are presented as the total Part D net payment, estimated as the Medicare covered amount plus the low income subsidy amount (LIS). Out-of-pocket cost is estimated as patient pay amount plus the True Out-of-Pocket Costs (TrOOP) amount. Table 12.6 shows six common prescribed Part D drug classes (based on the Anatomical Therapeutic Chemical (ATC) Classification System and the National Drug Code Directory from the Food and Drug Administration (FDA)) by cost and percentage of patients with any prescription filled.

Chapter 13: International Comparisons

Data Collection

Each country was provided a data-collection form spreadsheet (Microsoft Excel) to complete for years 2008 through 2013. Countries were asked to report patient count data for each year, if available, for the entire population, by sex (male, female), or by five different age categories (0–19, 20–44, 45–64, 65–74, 75+) for: (1) the country's or region's general population; (2) patients new to ESRD during the year; (3) patients new to ESRD during the year among new ESRD patients for whom DM was the primary cause of ESRD; (4) the point-prevalent count of ESRD patients living on December 31 of the given year; (5) total number of patients with a functioning kidney transplant on

December 31st of the given year; (6) total number of kidney transplants performed during the year, by type of kidney transplant (cadaveric, living donor, other donor); and (7) the number of dialysis patients, HD patients, CAPD/APD/ IPD patients, and home HD patients on December 31st of the indicated year. Prevalence was reported for all patients at the end of the calendar year (December 31, 2013), except where otherwise noted. Data for Italy, South Africa, and Lebanon were taken directly from the respective registry's annual report (McDonald et al., 2013; Italian Registry of Dialysis and Transplant, 2014; Davids et al., 2014; Elzein, 2012). Information for Ukraine was based on a recent publication of registry data from Ukraine (Kolesnyk et al., 2014). Data provided by Argentina may be supplemented by Marinovich et al., 2014.

Data Loading and Cleaning

The data were imported into SAS from Microsoft Excel and data quality checks were performed, with follow-up with registries, as needed. The global map was created using the Google Developers Visualization GeoChart API in JavaScript. The base image was then uploaded into Microsoft PowerPoint 2010.

Statistical Analyses

Incidence and prevalence were calculated as the count divided by the total population for that year, multiplied by one million. For age-specific and sex-specific categories, incidence and prevalence were calculated as the count in each category divided by the total population in the category, multiplied by one million.

To contribute data from your country's registry, please contact *international@usrds.org*.

Chapter 14: USRDS Special Study Center on Palliative and End-of-Life Care

Methods for the creation of the figures and tables in Chapter 14 are described within the chapter itself.

ESRD Reference Table Methods

Reference Section A: Incidence

The Reference Tables present parallel sets of counts and rates for incidence (Section A) and December 31 point prevalence (Section B). Section B also presents annual period prevalent counts and counts of lost-to-follow-up patients. Because the U.S. population figures (shown in Reference Section M) used in the ADR include only residents of the 50 states and the District of Columbia, tables also focus on patients from these areas. Exceptions are Tables A.1, A.6, A.8, and A.10, all of which present data specific to patients in Puerto Rico and the U.S. territories, or include these patients in the patient population. Age is computed as of the beginning of ESRD therapy.

Rates in Table A.2, A.9 and A.11 are adjusted for age, sex, race, and ethnicity with the 2011 national population as reference.

Reference Section B: Prevalence

With the exception of Tables B.1, B.6, B.8, and B.10, these tables focus on patients in the 50 states and the District of Columbia. Age is calculated as of December 31. Rates in Table B.2, B.9 and B.11 are adjusted for age, sex, race, and ethnicity with the 2011 national population as reference.

Reference Section C: Patient Characteristics

Data in these tables are based on information collected with the 1995 and 2005 Medical Evidence 2728 forms. Table C.1 contains data on biochemical markers from 2005–2013. A new Medical Evidence form (CMS 2728) was introduced in 2005 that included glycosylated hemoglobin (HbA1c), total cholesterol, low-density lipoprotein, high-density lipoprotein and triglycerides. Because these data elements had not been collected on the previous form, values are not available for the first few months of 2005. Data prior to 2005 on mean values reported for these markers may be unreliable due to low numbers of patients. Blood urea nitrogen was dropped from the 2005 form, and in later years Tables C.1(2) and C.1(3) BUN cells are blank because of this change.

Reference Section D: Treatment Modalities

Reference Section D is divided into four parts. The first, Tables D.1–D.11 and D.15–D.16, provides counts and percentages—by demographics, geographic location, and treatment modality—of incident and prevalent patients alive at the end of each year. Age is computed as of the start of ESRD for incident patients and as of December 31 for point prevalent patients.

Table D.12 shows modality at day 90 and at two years after first service for all incident Medicare patients beginning renal replacement therapy from 2009–2011. The 90-day rule is used to exclude patients who die during the first 90 days of ESRD, and age is computed as of the first ESRD service date.

The third section, Tables D.13–D.14, presents counts of prevalent patients alive at the end of each year, by ESRD exposure time and modality. Table D.13 shows counts by the number of years of ESRD, while Table D.14 presents counts by the number of years on the end-of-year treatment modality. For the duration of ESRD exposure, zero should be read as less than one year, one as at least one full year, but less than two, and so on.

The fourth section, Tables D.17–D.24, presents counts of incident and prevalent patients alive at the end of selected years (i.e., 2005, 2009, 2013), by demographic characteristics, payer category, and treatment modality. Again, age is computed as of the start of ESRD for incident patients and as of December 31 for point prevalent patients. The payer categories are:

- Medicare FFS (i.e., Medicare as primary payer)

- Medicare/Medicaid (i.e., dually eligible)

- MSP (i.e., Medicare as secondary payer): EGHP and non-EGHP

- HMO (i.e., Medicare Advantage or Medicare+Choice plans)

- Other and unknown payers

The detailed discussion of payer categories can be found in the *Database Definitions* section at the beginning of this chapter.

REFERENCE SECTION E: TRANSPLANTATION

Tables E.1–E.5 present data regarding the kidney transplant waiting list. Table E.1 presents counts of ESRD-certified candidates newly added to the waiting list for a kidney or kidney-pancreas transplant during the given year. Patients listed at multiple transplant centers are counted only once. Table E.2 presents wait times, defined as the median time in days from first listing to transplant among patients listed for a kidney-alone transplant, and is estimated with the Kaplan-Meier method. Patients listed at multiple centers are counted from the time of the first listing. The data are censored at the loss-of-follow-up, death, or the 'end-of-study' (which is 2013 for the 2015 Reference Table). Given that the median waiting time is about four years, the value cannot be estimated reliably without at least 4 year of follow-up. As a result, the 2015 Table E.2 only shows data up to year 2009. Table E.3 presents counts of ESRD-certified patients on the waiting list at any transplant center on December 31 of the given year, regardless of when the first listing occurred. Table E.4 includes point prevalent dialysis patients wait-listed

for a kidney on December 31 of the given year. Table E.5 presents the percentage of patients wait-listed or receiving a transplant within one year of ESRD initiation. Patients receiving a deceased donor kidney transplant are included in Tables E.5, E.5.3, and E.5.4, and patients receiving a deceased or live donor kidney transplant are included in Tables E.5.2, E.5.5, and E.5.6. Percentages in Tables E.2 and E.5 are calculated using the Kaplan-Meier method.

Transplant counts are presented in Tables E.6–E.8. All kidney transplants, including kidney-alone and kidney plus at least one other organ, are included unless specified in the footnote, and all counts include non-Medicare patients. Table E.8 illustrates the distribution of recipients by donor type and panel reactive antibody level, determined from the OPTN Recipient Histocompatibility form, and shows a cross-tabulation of recipients and donors in terms of cytomegalovirus antibody status, hepatitis C antibody status, and Epstein-Barr antibody status at the time of transplantation. A recipient/donor is considered positive for any of these antibodies if any applicable OPTN data source indicates positive. Unknown status is applied when no applicable data fields indicate "positive" or "negative." In Table E.8.2, cold ischemia time (in hours) is reported for deceased donor transplants only, and is taken from the OPTN Transplant Recipient Registration form.

Transplant rates per 100 dialysis patient years are shown in Table E.9. All HD patients, PD (CAPD/CCPD) patients, and patients on an unknown form of dialysis are included, as are all non-Medicare dialysis patients. A patient's dialysis days are counted from the beginning of the specified year, or from day one of ESRD dialysis therapy if treatment begins within the specified year, until transplant, death, or the end of the year, whichever comes first. Dialysis time for patients returning to dialysis from transplant is counted. Transplant rates are calculated as the number of transplants, including kidney-alone and kidney plus at least one other organ, divided by the total number of dialysis patient years for each year.

REFERENCE SECTION F: TRANSPLANTATION: OUTCOMES

This section presents probabilities of graft survival and graft failure necessitating dialysis or repeat transplantation, by donor type, age, sex, race, ethnicity, primary cause of ESRD, and first versus subsequent transplant. Data are presented for outcomes at 90 days, one year, two years, three years, five years, and ten years

post-transplant. This section seeks to address two major issues: the probability of graft survival at various times post-transplant, and the probability that a recipient will return to dialysis or require repeat transplantation at various times post-transplant. Recipients are followed from the transplant date to graft failure, death, or the end of the follow-up period (December 31, 2013). In the analysis of graft survival, death is considered a graft failure. In the analysis of graft failure necessitating dialysis or repeat transplantation, patients are followed until graft failure (excluding death), and patient follow-up is censored at death. To produce a standard patient cohort, patients with unknown age or sex are omitted. Unknown age is defined as a missing age at transplant, or an age calculated to be less than zero or greater than 100 years. Patients are also excluded if their first ESRD service date is prior to 1977.

Unadjusted survival probabilities are estimated using the Kaplan-Meier method, while the Cox proportional hazards model is used for adjusted probabilities. Probabilities are adjusted for age, sex, race, primary cause of ESRD, and first versus subsequent transplant, and standardized to 2011 recipient characteristics.

REFERENCE SECTION G: MORBIDITY AND HOSPITALIZATION

Hospitalization Reference Tables present adjusted total admission and hospital day rates, by year, 2004–2013. The model-based adjustment method used in these tables is discussed later in this section and in the *Statistical Methods* section at the end of this chapter.

Because hospitalization data for non-Medicare patients may be incomplete, analyses in this section include only patients with Medicare as their primary payer. Hospitalization data are obtained from institutional inpatient claims. As in Chapter 5, hospitalization data in *Reference Section G: Morbidity and Hospitalization* do not exclude inpatient stays for the purpose of rehabilitation therapy.

Tables G.1–G.15 include dialysis and transplant patients who are on their modality for at least 60 days, reaching day 91 of ESRD by the end of the year, and residing in the 50 states, the District of Columbia, Puerto Rico, and the U.S. territories. Excluded are patients with AIDS as a primary or secondary cause of death; patients with missing values for age, sex, or race; and patients of races that are unknown or other than White, Black/African American, Native American, or Asian. Age is determined on January 1

of each year. Patients are also classified according to their primary cause of ESRD, in which the "other" category includes patients with missing data or causes other than diabetes mellitus (DM), hypertension, or glomerulonephritis.

Patients are classified by modality at the beginning of the year:

- All dialysis: patients on HD, CAPD/CCPD, or dialysis of an unknown type, as well as those on more than one modality in the past 60 days

- Hemodialysis: patients on HD for at least 60 days as of the start of the period at risk

- CAPD/CCPD: patients on CAPD/CCPD for at least 60 days as of the start of the period at risk

- Transplant: patients with a functioning transplant, and who received the transplant less than three years prior to the start of the period at risk

- All-ESRD: all patients

To limit the contribution of patient years at risk from patients who do not have Medicare coverage but do have Medicare as a secondary payer or HMO coverage, and who therefore have incomplete hospitalization data, cohorts include only patients with Medicare Parts A and B coverage at the start of follow-up. The follow-up period is censored when a patient's payer status changes to no longer having Medicare Parts A and B coverage or Medicare as a primary payer.

For patients in the all-dialysis, HD, and PD categories, the period at risk for all hospitalization analyses is from January 1 or day 91 of ESRD until the earliest of death, three days prior to transplant, end of Medicare Parts A and B coverage, or December 31. Modality change is considered a censoring event only in the case of a change from dialysis to transplant. For dialysis patients in the all-ESRD category, in contrast, the analysis period is censored only at death, end of Medicare Parts A and B coverage, or December 31 of the given year; a modality change is not used as a censoring event. For transplant patients in the all-ESRD and transplant categories, the period is censored at the earliest of death, three years after the transplant date, end of Medicare Parts A and B coverage, or December 31 of the given year. The censoring of transplant patients at three years following the transplant is necessary because Medicare eligibility may be lost and hospitalization data may be incomplete for these patients.

Time at risk is calculated differently for hospital days and total admissions. Since a hospitalized patient

remains at risk for additional hospital days, rates for hospital days include hospital days in the time at risk value. Since a currently hospitalized patient is not, however, at risk for new admissions, hospital days for each year are subtracted from the time at risk for total admissions. In the case of a hospitalization in which admission occurs the same day as discharge, zero days are subtracted from the time at risk for total admissions. When hospitalizations span the start of the analysis period, only the days within the period are subtracted from the time at risk for total admissions.

All admissions and hospital days during the analysis period are included, respectively, in the total admissions and hospital days for each year. An admission for a hospitalization that occurs before and spans the start of the analysis period is excluded from the total admissions for that period, and only the hospitalization days within the period are counted in the total days for hospital day rates. The minimum length of stay is one day, and hospitalizations with an admission and discharge on the same day, as well as those with a discharge the day after admission, are both counted as one day.

As in previous ADRs, all overlapping and only certain adjacent hospitalizations are combined, due to the fact that many adjacent claims may actually be legitimate separate hospitalizations. Specifically, hospitalizations with an admission on the same day or the day after a previous discharge are combined only when there is a discharge transfer code or indication of an interim claim. In the case of two hospitalizations combined into one, the principal diagnosis and procedure codes are retained from the first of the two hospitalizations, with the combined hospitalization extending from the first admission date to the last discharge date.

The methodology for computing adjusted total admission and hospital day rates uses the model-based adjustment method (discussed in the section on statistical methods). Predicted rates for each subgroup combination of age, sex, race, primary cause of ESRD, and year are obtained using a model with the Poisson assumption. For prevalent patient cohorts, this model uses data from the current and previous two years, with respective weights of 1, 1/4, and 1/8. Adjusted rates are then calculated using the direct adjustment method, with all 2011 ESRD patients as the reference cohort.

Tables G.11–G.15 show inpatient utilization in the period prevalent ESRD patients. Methods—including modality definitions, inclusion criteria, data cleaning, follow-up time definitions, and rate calculations—generally follow

those described for the total admission rates in Tables G.1–G.5, but some differences do exist. While patients of races other than White, Black/African American, Native American, or Asian are excluded from G.1–G.5, they are included in G.11–G.15, except where rates are given by race. Rates are unadjusted and reflect total admissions per 100 patient years for 2005–2007, 2008–2010, and 2011–2013 (pooled) prevalent patients. While the rates for all causes are computed similarly to the unadjusted rates in G.1–G.5, the other nine cause-specific categories only include admissions for specific diseases. Vascular access and PD access hospitalizations are those classified as "pure" inpatient vascular/dialysis access events. Such access events are defined as admissions with a specified ICD-9-CM principal diagnosis code, or an ICD-9-CM principal procedure code in conjunction with a certain Diagnosis Related Group (DRG) code. Codes are listed in Table m.4. If an admission does not qualify as vascular/dialysis access, it is classified by the principal diagnosis code into one of eight other mutually exclusive groups. Categories and ICD-9-CM codes are as follows: circulatory diseases, 390–459; digestive diseases, 520–579; genitourinary diseases, 580–629; endocrine and metabolic diseases, 240–279; respiratory diseases, 460–519; infectious diseases, 001–139; and cancer, 140–172, 174–208, 230–231, and 233–234. Hospitalizations that do not fall under any of these categories are counted under all others.

vol 2 Table m.4 DRG & ICD-9-CM codes for vascular access & peritoneal dialysis access variables

DRG codes[a] prior to October 1, 2007

112 Percutaneous cardiovascular procedure

120 Other circulatory system OR procedure

315 Other kidney and urinary tract OR procedure

442 Other OR procedure for injuries with complication

443 Other OR procedure for injuries without complication

478 Other vascular procedure with complication

479 Other vascular procedure without complication

DRG codes[a] after September 30, 2007

252 Other vascular procedures with Major complicating conditions (MCC)

264 Other circulatory system O.R. procedures

673 Other kidney & urinary tract procedures with MCC

674 Other kidney & urinary tract procedures with CC

675 Other kidney & urinary tract procedures without CC/MCC

907 Other O.R. procedures for injuries with MCC

908 Other O.R. procedures for injuries with CC

909 Other O.R. procedures for injuries without CC/Medicare

ICD-9-CM procedure codes[a]

38.95 Venous catheterization for renal dialysis

39.27 Arteriovenostomy for renal dialysis

39.42 Revision of arteriovenous shunt for renal dialysis

39.43 Removal of arteriovenous shunt for renal dialysis

39.93 Placement of vessel-to-vessel cannula

39.94 Replacement of vessel-to-vessel cannula

86.07 Placement of totally implantable vascular access device

ICD-9-CM diagnosis codes[b]

996.1 Mechanical complication of vascular device, implant, graft

996.56 Mechanical complication due to peritoneal dialysis catheter

996.62 Infectious complication of vascular device, implant, graft

996.68 Infectious complication due to peritoneal dialysis catheter

996.73 Other complication due to renal dialysis device, implant, graft

999.31 Infection due to central venous catheter

V56.1 Fitting and adjustment of extracorporeal dialysis catheter

V56.2 Fitting and adjustment of peritoneal dialysis catheter

[a] DRG and procedure codes are used in conjunction to define inpatient pure vascular access events (both must be present).
[b] The presence of any of these diagnosis codes as the "Principal Diagnosis Code" is sufficient to define an inpatient pure vascular access or peritoneal dialysis access event.

Tables G.1.1–G.5.1 present adjusted rates similar to those shown in G.1–G.5, but include more patient subgroups. Additionally, Tables G.1.2–G.5.2 display the counts of the total admissions, patient years at risk, and total patients that are used to calculate the total admission rates.

Reference Section H: Mortality and Causes of Death

Cohorts for tables in Section H include both Medicare and non–Medicare patients living in the 50 states, the District of Columbia, Puerto Rico, and the U.S. territories. The 60-day stable modality rule and 90-day rule are not applied to tables in Section H.

The cohorts in Tables H.1–H.12 are comprised of period prevalent patients, including those alive on January 1 and those incident during a calendar year. All patients are followed from either January 1 (for those alive on January 1) or from the date of onset of ESRD (for those patients incident in a calendar year). Follow-up is censored at loss to follow-up, date of transplant (for dialysis patients), recovery of function, or December 31 of the year. Age is defined at the beginning of follow-up. In calculating adjusted mortality, beginning in 1996, we have adjusted and reported for five race groups (White, Black/African American, Native American, Asian, and Other), as well as for ethnicity (Hispanics and non-Hispanics).

Tables H.1, H.2, and H.2.1 present mortality data for all ESRD patients. Total deaths are presented in Table H.1. Overall unadjusted and adjusted annual mortality rates by age, sex, race/ethnicity, primary cause of ESRD, and years of ESRD treatment are presented in Table H.2. Category-specific unadjusted mortality rates are calculated as total patient deaths divided by total follow-up time. Adjusted rates are computed by an appropriately weighted average of predicted category-specific rates, with the predicted rates based on generalized linear mixed models. Such methods, akin to direct standardization, are described in the *Statistical Methods* section later in this chapter. Overall mortality rates are adjusted for age, sex, race, primary cause of ESRD, and years of ESRD treatment, while rates for each individual category are adjusted for the other four factors. The reference population includes 2011 prevalent ESRD patients. Table H.2.1 presents unadjusted mortality rates by age, sex, race, and primary cause of ESRD for 2013 prevalent ESRD patients; rates are again smoothed using a generalized linear mixed model.

The same methods are used for Tables H.3, H.4, and H.4.1 (dialysis); H.5 (dialysis patients, never on transplant waiting list); H.6 (dialysis patients on transplant waiting list); H.7 (dialysis patients, returned to dialysis from transplant); H.8 and H.8.1 (HD); H.9 and H.9.1 (CAPD/CCPD); and H.10 and H.10.1 (transplant).

For Table H.13, general U.S. population life expectancy, the data source is Table 7 in the National Vital Statistics Report (NVSR), Deaths: Final Data for 2012. The methodology used is different from previous years: the expected remaining lifetime reported for a five year age range is the mean of the values for the starting age and the ending age. For example, the value reported for the 15–19 year old age group is the average of the values at the exact ages 15 and 20. For the age group 0–14 years old, the number reported is the mean of the values for the exact ages of 0, 1, 5, 10 and 15. Similarly, the life expectancy of the age 85+ group is the mean of the values for the exact ages of 85, 90, 95 and 100.

REFERENCE SECTION I: PATIENT SURVIVAL

These tables present patient survival probabilities, based on incident cohorts. All causes of death are included, as are all non-Medicare patients and patients living in the 50 states, the District of Columbia, Puerto Rico, and the U.S. territories. Patients were excluded if sex is unknown, or if age is unknown. All new ESRD patients with a first ESRD service date between January 1, 1996 and December 31, 2012, are included in the analysis. These patients are followed from day one (ESRD onset) until death, loss to follow-up, or December 31, 2013. For dialysis patients, both HD and PD, follow-up is also censored at recovery of native renal function and at receipt of a kidney transplant. Unadjusted patient survival probabilities are estimated using the Kaplan-Meier method, while adjusted survival is computed through model-based direct standardization using Cox regression. Incident 2011 ESRD patients served as the reference population for both overall and subgroup-specific adjusted survival.

REFERENCE SECTION J: PROVIDERS

In Reference Section J, we define a chain-affiliated unit as a freestanding dialysis unit owned or operated by a corporation at the end of a year. The category of small dialysis organization (SDO) includes all organizations meeting our definition of a chain but not owned by DaVita, Fresenius Medical Care (Fresenius), or Dialysis Clinic, Inc. (DCI).

Data are obtained from CMS's Annual Facility Survey (1988 to the present), Renal Dialysis Facilities Cost Report (Form 265–94, 1994–2000), and Dialysis Facility Compare (DFC) database (2001 to the present), as well as the CDC National Surveillance of Dialysis-Associated Diseases in the United States (1988–2002, excluding 1998, when the CDC did not conduct a survey). The CDC discontinued the National Surveillance of Dialysis-Associated Diseases after 2002.

A facility's hospital-based or freestanding status is determined from the third and fourth digits of the provider number assigned to each unit by CMS. A facility's profit status is determined through the ownership type field on the CMS survey (for years prior to 2001) or the profit status field of the DFC database (2001 to the present).

REFERENCE SECTION K: MEDICARE CLAIMS DATA

Cost information in this section is derived from Medicare inpatient, outpatient, skilled nursing facility, hospice, home health, physician/supplier, durable medical equipment, and Part D claims data in the CMS SAFs, which are created annually six months after the end of each calendar year. Claims data are obtained for all patient identification numbers in the USRDS Database. The claims data are then merged with patient demographic data and modality information in the USRDS Database.

The economic analyses for this section focus on the claim payment amount, which is the amount of the payment made from the Medicare trust fund for the services covered by the claim record. These analyses also include the pass-through per diem amount, which applies to inpatient claims and reimburses the provider for capital-related costs, direct medical education costs, and organ acquisition costs.

The Reference Tables in section K exclude patients who were classified as MSP and individuals with missing values for demographics, modality, or payer status, unless otherwise specified.

Payer Sequence

The payer sequence is similar in concept to the USRDS treatment history. Payer status is tracked for each ESRD patient from the first ESRD service date until death or the end of the study period. Data from the Medicare Enrollment Database and dialysis claims information are used to categorize payer status as Medicare primary payer (MPP), Medicare secondary payer (MSP), or non-Medicare. The claims database contains data only for MPP and MSP patients, so economic analyses are restricted to these categories. In addition, as it is impossible to determine the complete cost of care for ESRD patients with MSP coverage,

analyses of costs per person per year exclude patients during the periods when they have this coverage.

Payment Categories

Medicare payments are broken into several categories. Estimates of costs from the outpatient SAF are derived for the individual services provided. Since complete data on line-item payments are available starting with the 2001 outpatient SAF, the estimates for outpatient payment categories are taken directly from the claims data for calendar years 2004–2013, with adjustments as noted.

Model 1: As-treated actuarial model

In an as-treated model patients are first classified by their modality at entry into the analysis, and retain that classification until a modality change. When a change is encountered in the data, the initial modality is censored, and a new observation with the new modality is created. Under this method, aggregation of Medicare payments is done on an as-treated basis, attributing all payments for a particular claim to the patient's modality at the time of the claim.

In Section K of the Reference Tables, we classify patients into four as-treated modality categories: HD, CAPD/CCPD, other dialysis, and transplant. The "other dialysis" category includes cases in which the dialysis modality is unknown or is not HD or CAPD/CCPD, while the transplant category includes patients who have a functioning graft at the start of the period, or who receive a transplant during the period. Some tables also include categories for all dialysis (HD, CAPD/CCPD, and other dialysis) and all ESRD (all-dialysis and transplant).

The study spans the 10 years from January 1, 2004 to December 31, 2013, and ESRD patients prevalent on January 1, 2004, or incident at any time during the period are potentially eligible for inclusion. The initial study start date for a given patient is defined as the latest of January 1, 2004, or the first ESRD service date in the USRDS Database for that patient. Claims during periods that a patient is classified as MSP are included in Tables K.1–K.4, and are excluded for the rest of the tables in Section K.

To express costs as dollars per year at risk, total costs during the follow-up period are divided by the length of the period. Costs per patient year at risk are calculated by patient category, and stratified by age, sex, race, modality, and diabetic status (based on the patient's primary cause of ESRD).

Model 2: Categorical calendar year model

This model, described in the Health Care Financing Administration (now CMS) research report on ESRD (1993–1995), is used for Reference Tables K.10–K.13. With this method, patients are classified into four mutually exclusive treatment groups:

- Dialysis: ESRD patients who are on dialysis for the entire calendar year, or for that part of the year in which they are alive and have ESRD

- Transplant: ESRD patients receiving a kidney transplant during the calendar year

- Functioning graft: ESRD patients with a functioning graft for the entire calendar year, or for that part of the year in which they are alive and have ESRD

- Graft failure: ESRD patients who have had a transplant, but return to dialysis due to loss of graft function during the calendar year; patients with a graft failure and a transplant in the same calendar year are classified in the transplant category

REFERENCE SECTION L: VASCULAR ACCESS

Tables L.1–L.6 include period prevalent HD patients with Medicare as primary payer. Placements are identified from Medicare claims, and rates represent the total number of events divided by the time at risk. Follow-up is censored at death, change in modality, change in payer status, or the end of the prevalent year.

Tables L.7–L.8 include point prevalent PD patients with Medicare as primary payer. Complications are obtained from claims during the time at risk in the prevalent year, and rates represent the total number of events divided by the time at risk. Follow-up time is censored at death, a change in modality, a change in payer status, a claim for HD vascular access placement, or at the end of the prevalent year.

REFERENCE SECTION M: CENSUS POPULATIONS

Table M.1 includes the U.S. resident population on July 1 for year 1996–2013. The data sources are U.S. census, intercensal and postcensal population estimates from the CDC Bridged-Race Population Database. They are used to calculate incidence and prevalence rates.

Statistical Methods

METHODS FOR CALCULATING RATES

The calculation of observed rates is straightforward, with some rates based on counts and others on follow-up time. The ESRD incident rate in 2009, for example, is the observed incident count divided by the 2009 population size and, if the unit is per million population, multiplied by one million. The 2009 death rate for prevalent ESRD patients is the number of deaths in 2009 divided by the total follow-up time (patient years) in 2009 of the 2009 prevalent patients, and, if the unit is per thousand patient years, multiplied by one thousand. Standard errors of estimated rates are based on the assumption of the data; the observed count has a Poisson or binomial distribution. The count-based rate describes the proportion having the "event," and the time-based rate tells how often the "event" occurs.

Model-based Rates

Some patient groups may be very small, and their observed rates are, therefore, unstable. If follow-up time is considered, the hazard of an event may change over time. A model-based method can improve the stability of these estimates and incorporate changes of hazard over time. In this ADR, for example, we have used the generalized linear mixed Poisson model to estimate prevalent patient mortality rates for *Reference Section H: Mortality and Causes of Death*.

Measurement Unit for Rates

Both observed and model-based rates are calculated per unit of population (i.e., per 1,000 patients) or per unit of follow-up time (i.e., per 1,000 patient years). Calculating rates per unit of follow-up time can account for varying lengths of follow-up among patients. Patient years are calculated as the total number of years, or fractions of a year, of follow-up time for a group of patients.

Take, for example, a calculation of 2010 first hospitalization rates for two groups of patients, all receiving dialysis therapy on January 1, 2010. Group A consists of three patients: patient one had a first hospitalization on March 31, 2010; patient two was hospitalized on June 30, 2010, and patient three was on dialysis through December 31, 2010; with no hospitalizations. Group B also has three patients: patient four was first hospitalized on December 31, 2010; patient five was hospitalized on September 30,

2010; and patient six was on HD the entire year, with no hospitalizations through December 31, 2010.

Patients one to six contribute 0.25, 0.5, 1.0, 1.0, 0.75, and 1.0 patient years at risk, respectively. The first hospitalization rate per thousand patients is 667 for both groups in 2010. But the first hospitalization rate per thousand patient years at risk is 1,143 for Group A and 727 for Group B (calculated as [2 total events / 1.75 total patient years at risk] x 1,000 for Group A and [2 total events / 2.75 patient years at risk] x 1,000 for Group B). The resulting rate is lower for Group B because of the longer total follow-up time.

Rates per unit of population may be influenced by the proportion of patients who are followed for only a fraction of a year. The event rate per unit of population is likely to be lower, for example, in a group of patients followed for only one month until censoring than in a group whose patients are each followed for up to a full year. Rates per unit of follow-up time at risk, in contrast, count only the actual time that a patient is at risk for the event.

METHODS FOR ADJUSTING RATES

Because each cohort contains a different patient mix, observed event rates may not be comparable across cohorts. Adjusted analyses make results comparable by reporting rates that would have arisen had each cohort contained patients with the same distribution of confounders—such as age, sex, race, and primary cause of ESRD—as the reference population.

Direct Adjustment

There are several rate-adjustment methods, but only the direct method allows rates to be compared (Pickle & White, 1995). Here the adjusted rate is derived by applying the observed category-specific rates to a single standard population (i.e., the rate is a weighted average of the observed category-specific rates, using as weights the proportion of each category in the reference population). Categories are defined by the adjusting variables. For example, if a rate is adjusted for race and sex and there are three race groups (White, Black/African American, and Other) and two sex groups, there are six categories: White males, White females, Black/African American males, Black/African American females, males of other races, and females of other races.

Suppose we try to compare state-level incidence rates in 2009 after removing the difference caused by

race. To do this, we need to calculate the incidence rate, adjusted for race, for each state. Because racial distributions in each state are quite different, we use as reference the national population—here, the population at the end of 2009—with five race groups (White, Black/African American, Native American, Asian, and Other).

Assuming the incidence rate of state A in 2009 is 173 per million population, and the race-specific rates and race distribution of the national populations are as shown in Table m.5 below, the adjusted incidence rate of state A with the national population as reference is (153 x 75.1%) + (250 x 12.3%) + (303 x 0.9%) + (174 x 3.6%) + (220 x 8%) = 158.73 per million population. This means that if state A had the same racial distribution as the entire country, its incidence rate would be 158.73 instead of 173. If state B had an adjusted incidence rate of 205, we could say that state B had a higher incidence rate than state A if they both had the same racial distribution as the whole country.

vol 2 **Table m.5 Example of adjusted incident rate calculation**

	Incidence rate of State A	National population (%)
White	153	75.1
Black/African American	250	12.3
Native American	303	0.9
Asian	174	3.6
Other	220	8.0

This method is used to produce some adjusted incidence and prevalence rates in Chapters 1 and 3, and in Reference Sections A and B, as well as in the model-based adjustment method.

Model-based Adjustment

Under some circumstances there are disadvantages to the direct adjustment method. Suppose we are calculating mortality rates for a set of groups, and adjusting for potential confounding variables. If one category in a group has only a few patients or deaths, its estimated category-specific mortality rate will be unstable, likely making the adjusted rate unstable as well. In addition, if one includes a category with no patients, the method is not valid for calculating an adjusted mortality rate for the group. An attractive alternative is a model-based approach, in which we find a good model to calculate

category-specific estimated rates for each group, and then calculate direct adjusted rates using these estimates with a given reference population. This method can also be extended to adjustments with continuous adjusting variables (Liu et al., 2006). As in previous ADRs, standard errors of the adjusted rates are calculated using a bootstrap approach. In general, the bootstrap approach works well, but is time consuming. Convergence problems occur in a few bootstrap replications and such cases are ignored in the calculation. In this ADR we use model-based adjustments to calculate adjusted mortality rates, adjusted hospitalization rates, and state-level adjusted incidence and prevalence rates using the Poisson model and some other rates, as described in the text on the individual figures.

Survival Probabilities and Mortality Rates

Unadjusted Survival Probabilities

In this ADR, unadjusted survival probabilities are calculated using the Kaplan-Meier method, and corresponding standard errors are calculated with Greenwood's formula (Kalbfleisch & Prentice, 2002). Survival probabilities in *Reference Section I: Patient Survival* are expressed as percentages from 0 to 100. The mortality/event rate in the period of (0,t) is calculated by [-ln(Survival at time t)]. This event rate will be the same as that estimated by event time divided by follow-up time after adjustment of the unit, if the event rate is a constant over time.

Survival Probability With Competing Risks

When competing risks exist, the estimate of the cumulative incidence function of a specific cause may be biased if the other competing risks are ignored. If we have K competing risks, the cumulative incidence function of cause k, k=1, 2, …, K, at time t, $I_k(t)$, is defined as the probability of failing from cause k before time t (including time t), Prob(T≤t, D=k). Then

$$I_k(t) = \int_0^t \lambda_k(s)S(s)ds$$

where $\lambda_k(s)$ is the hazard of event from cause k at time s and S(s) is the survival probability at time s (the probability of no event happening). If we have failing time t_1, t_2, …, t_m, the cumulative incidence function of cause k at tim

$$I_k(t) = \sum \hat{\lambda}_k(t_j)\hat{S}(t_j - 1)$$

Where $\hat{\lambda}_k(t_j) = D_{kj}/n_j$, $\hat{S}(t_j - 1)$ is the Kaplan-Meier estimate of survival at time t_j-1, D_{kj} is the number of

patients failing from cause k at time t_j, and n_j is the number of patients at risk at prior time t_j (Putter et al., 2007).

Adjusted Survival Probabilities

Adjusted survival probabilities are reported in *Reference Section I: Patient Survival,* with age, sex, race, Hispanic ethnicity, and primary cause of ESRD used as adjusting risk factors. The model-based adjustment method is used, with survival probabilities/conditional survival probabilities predicted from the Cox regression model (Kalbfleisch & Prentice, 1980, 2002). This process yields estimates of probabilities that would have arisen in each year if the patients had had the same attributes as the reference population. Since the probabilities in each table are adjusted to the same reference set of patient attributes, any remaining differences among cohorts and years are due to factors other than age, sex, race, Hispanic ethnicity, and primary cause of ESRD. The adjusted mortality rates for incident cohorts in *Reference Section H: Mortality and Causes of Death* are calculated using similar methods.

Generalized Linear Models

Generalized Linear Mixed Model for Mortality Rates

We use the generalized linear mixed model with log link and Poisson distribution to calculate mortality and first transplant rates for prevalent patients. While rates are reported for a year, data from the previous two years with different weights are also used to improve the stability of the estimates.

The generalized linear mixed model, which considers both fixed and random effects, is implemented using the SAS macro GLIMMIX. Rates for the intersections of age, sex, race, and diagnosis are estimated using the log linear equation Log (rate) = (fixed effects) + (random effect). Fixed effects include year, age, sex, race, and primary cause of ESRD, and all two-way interactions among age, sex, race, and primary cause of ESRD. Assumed to be independently and identically distributed with a normal distribution, the random effect is the four-way interaction of age, sex, race, and primary cause of ESRD. Age is used as a categorical variable.

For tables with mortality rates for both intersecting and marginal groups, we have used a single model to calculate all rates in each table. The marginal rates are simply the weighted averages of the estimated, cross-classified rates, with cell-specific patient years as weights. For this approach, the use of a single

model means that GLIMMIX cannot give the standard errors for some of these estimated rates; the bootstrap method is, therefore, used instead.

The adjusted mortality rates for prevalent cohorts in *Reference Section H: Mortality and Causes of Death* are calculated using the direct adjustment method based on the category-specific mortality rates from the generalized linear mixed models.

Generalized Linear Model for Hospitalization Rates

In this ADR, hospitalization Reference Tables present rates of total admissions and hospital days. We use a generalized linear model with log link and Poisson distribution; the model includes age, sex, race, primary cause of ESRD, and their two-way interactions.

To stabilize the estimates, three years of data are used with different weights. Year is also included in the model as a covariate. The adjusted hospitalization rates are calculated using the direct adjustment method, based on the category-specific admission rate from the generalized linear models.

Standardized Mortality Ratios

The standardized mortality ratio (SMR) compares the mortality of a group of patients relative to a specific norm, or reference, after adjusting for some important risk factors. For example, the dialysis chain-level SMR is used to compare mortality in prevalent dialysis patients—after adjusting for age, race, ethnicity, sex, DM, duration of ESRD, nursing home status, patient comorbidities at incidence, and BMI at incidence in each dialysis chain. Qualitatively, the degree to which the facility's SMR varies from 1.00 is the degree to which it exceeds (>1.00) or is under (<1.00) the national death rates for patients with the same characteristics as those in the facility. For example, an SMR=1.10 would indicate that the facility's death rates typically exceed national death rates by 10% (e.g., 22 deaths observed where 20 were expected, according to the facility's patient mix). Similarly, an SMR=0.95 would indicate that the facility's death rates are typically 5% below the national death rates (e.g., 19 observed versus 20 expected deaths). An SMR=1.00 would indicate that the facility's death rates equal the national death rates, on average. Note that if multiple years are included in fitting the model, the interpretation of the SMR for a particular year is different depending on whether calendar year is included in the model or not. If calendar year is included as an adjustment, the SMR for a particular

year compares facility outcomes to the national average rates for that particular year. On the other hand, if calendar year is not included, the comparison is to the national rates over the entire period included in fitting the model.

Method of SMR Calculation

The SMR is designed to reflect the number of deaths for the patients at a facility, relative to the number of deaths that would be expected based on overall national rates and the characteristics of the patients at that facility. Specifically, the SMR is calculated as the ratio of two numbers; the numerator ("observed") is the actual number of deaths, excluding deaths due to abused drugs and accidents unrelated to treatment, over a specified time period. The denominator ("expected") is the number of deaths that would be expected if patients at that facility died at the national rate for patients with similar characteristics. The expected mortality is calculated from a Cox model (Cox, 1972; SAS Institute Inc., 2004; Kalbfleisch and Prentice, 2002; Collett, 1994). The model used is fit in two stages. The Stage I model is a Cox model stratified by facility and adjusted for patient characteristics. This model allows the baseline survival probabilities to vary between strata (facilities), and assumes that the regression coefficients are the same across all strata. Stratification by facility at this stage avoids biases in estimating regression coefficients that can occur if the covariate distributions vary substantially across centers. The results of this analysis are estimates of the regression coefficients in the Cox model and these provide an estimate of the relative risk for each patient. This is based on a linear predictor that arises from the Cox model, and is then used as an offset in the Stage II model, which is unstratified and includes an adjustment for the race-specific age-adjusted state population death rates.

Standardized Hospitalization Ratios

The Standardized Hospitalization Ratios (SHR) for Admissions is designed to reflect the number of hospital admissions for the patients at a dialysis facility, relative to the number of hospital admissions that would be expected based on overall national rates and the characteristics of the patients at that facility. Numerically, the SHR is calculated as the ratio of two numbers: the numerator ("observed") is the actual number of hospital admissions for the patients in a facility over a specified time period, and the denominator ("expected") is the number of hospital

admissions that would have been expected for the same patients if they were in a facility conforming to the national norm.

The denominator of the SHR stems from a proportional rates model (Lawless and Nadeau, 1995; Lin et al., 2000; Kalbfleisch and Prentice, 2002). This is the recurrent event analog of the well-known proportional hazards or Cox model (Cox, 1972; Kalbfleisch and Prentice, 2002). To accommodate large-scale data, we adopt a model with piecewise constant baseline rates (e.g., Cook and Lawless, 2007) and the computational methodology developed in Liu, Schaubel and Kalbfleisch (2012). The modeling process has two stages. At Stage I, a stratified model is fitted to the national data with piecewise-constant baseline rates, stratification by facility and adjusting for age, sex, DM, duration of ESRD, nursing home status, comorbidities at incidence, BMI at incidence, and calendar year. The baseline rate function is assumed to be a step function with break points at 6 months, 1 year, 2 years, 3 years, and 5 years since the onset of dialysis. This model allows the baseline hospitalization rates to vary between strata (facilities), but assumes that the regression coefficients are the same across all strata; this approach is robust to possible differences between facilities in the patient mix being treated. The stratification on facilities is important in this phase to avoid bias due to possible confounding between covariates and facility effects. At Stage II, the relative risk estimates from the first stage are used to create offsets, and an unstratified model is fitted to obtain estimates of an overall baseline rate function.

Expected Remaining Lifetimes

The expected remaining lifetime for a patient group is the average of the remaining life expectancies for the patients in that group. Some patients will live longer than, and some will live less than, the average. Although the average cannot be known until all patients in the cohort have died, the expected remaining lifetime can be projected by assuming that patients in the cohort will die at the same rates as those observed among groups of recently prevalent ESRD patients.

For a subgroup of ESRD patients of a particular age, the expected remaining lifetime is calculated using a survival function, estimated for the group. Let $S(A)$ denote the survival function of patients at age A. Among patients alive at age A, the probability of surviving X more years is $S(X|A) = S(A+X)/S(A)$. For a given starting age A, the expected remaining lifetime is

then equal to the area under the curve of S(X|A) plotted versus X. Because few patients live beyond 100, this area is truncated at the upper age limit A + X = 100.

Half-lives (Median Time)

Conditional Half-life

The conditional half-life is conditional on having survived a given period of length T_0 without the event, the point at which 50% of patients who survived the given period remain alive. In other words, it is the median remaining lifetime conditional on surviving a given period T_0.

The conditional half-life is estimated using the Kaplan-Meier method if the median survival time falls in the duration of follow-up. Otherwise, the conditional half-life is estimated as the following:

Estimate the survival probabilities $S(t_0)$ and $S(t_1)$ using the Kaplan-Meier method from the data available, where $t_0 < t_1$ and T1 is within the follow-up

$$I_k(t) = \int_0^t \lambda_k(s)S(s)ds$$

the estimate of the conditional half-life = $\mu \cdot \ln(2)$.

This method can be used only when the hazard is a constant after t_0 and t_1 is chosen to be big enough to obtain a stable estimate of $\ln(S(t_0)) - \ln(S(t_1))$.

Mapping Methods

Throughout the ADR, data in maps and graphs are unadjusted unless otherwise noted. Because of area size and limitations in the mapping software, data for Puerto Rico and the U.S. territories are not included in the maps.

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